

25
No. 98-1152-CFX

Title: Food and Drug Administration, et al., Petitioners
v.
Brown & Williamson Tobacco Corporation, et al.

Docketed:
January 19, 1999

Court: United States Court of Appeals for
the Fourth Circuit

Entry Date

Proceedings and Orders

Jan 19 1999	Petition for writ of certiorari filed. (Response due March 22, 1999)
Jan 19 1999	Appendix of petitioner filed.
Jan 29 1999	Order extending time to file response to petition until March 22, 1999.
Jan 29 1999	This extension is granted for all respondents.
Feb 12 1999	Brief amicus curiae of Action on Smoking and Health filed.
Mar 17 1999	Waiver of right of respondents American Advertising Federation, et al. to respond filed.
Mar 22 1999	Brief amici curiae of Minnesota, et al. filed.
Mar 22 1999	Brief of respondents Brown and Williamson Tobacco Corp., et al. in opposition filed.
Mar 22 1999	Appendix of respondent filed.
Apr 7 1999	DISTRIBUTED. April 23, 1999
Apr 7 1999	Reply brief of petitioners Food and Drug Administration, et al. filed.
Apr 26 1999	Petition GRANTED. SET FOR ARGUMENT December 1, 1999. *****
May 18 1999	Order extending time to file petitioners' brief on the merits to and including July 12, 1999.
May 18 1999	Order extending time to file respondents' brief on the merits to and including September 10, 1999.
Jul 7 1999	Brief amici curiae of Public Citizen, Inc., et al. filed.
Jul 8 1999	Brief amicus curiae of Action on Smoking and Health filed.
Jul 9 1999	Brief amicus curiae of American College of Chest Surgeons filed.
Jul 12 1999	Joint appendix filed.
Jul 12 1999	Brief of petitioners Food and Drug Administration, et al. filed.
Jul 12 1999	Brief amici curiae of Minnesota, et al. filed.
Jul 12 1999	Brief amicus curiae of American Cancer Society, Inc. filed.
Jul 12 1999	LODGING consisting of ten copies of Volume Two of Regulation of Cigarettes and Smokeless Tobacco submitted by the Solicitor General
Sep 9 1999	Brief amicus curiae of Pacific Legal Foundation filed.
Sep 10 1999	Brief of respondent Brown and Williamson Tobacco Corp. filed.
Sep 10 1999	LODGING consisting of eleven sets of two volumes of a letter and industry comments submitted by counsel for Brown & Williamson.
Sep 10 1999	Brief of respondents United States Tobacco Company, et al. filed.
Sep 10 1999	Appendix of respondents United States Tobacco Company, et al. filed.
Sep 10 1999	LODGING consisting of twelve copies of a bound volume of

Entry Date

Proceedings and Orders

Regulatory, Congressional and Miscellaneous materials submitted by counsel for United States Tobacco Co., et al.

Sep 10 1999 Brief of respondent R.J. Reynolds Tobacco Company filed.

Sep 10 1999 LODGING consisting of eleven bound copies of twenty items submitted by counsel for R.J. Reynolds.

Sep 10 1999 Brief of respondents Natl. Association of Convenience Stores & Acme Retail, Inc. filed.

Sep 10 1999 LODGING consisting of ten copies of a bound volume of five items submitted by counsel for Natl. Assn. of Convenience Stores, et al.

Sep 10 1999 LODGING consisting of eleven sets of four bound volumes of material submitted by counsel for Philip Morris, et al.

Sep 10 1999 Brief of respondents Phillip Morris and Lorillard Tobacco filed.

Sep 10 1999 Brief amicus curiae of Washington Legal Foundation filed.

Sep 10 1999 Brief amicus curiae of Product Liability Advisory Council, Inc. filed.

Oct 6 1999 CIRCULATED.

Oct 12 1999 Reply brief of petitioners Food and Drug Administration, et al. filed.

Oct 13 1999 Record filed.

Oct 13 1999 Record filed.

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No.

OFFICE OF THE CLERK

In the Supreme Court of the United States

OCTOBER TERM, 1998

FOOD AND DRUG ADMINISTRATION, ET AL.,
PETITIONERS,

v.

BROWN AND WILLIAMSON TOBACCO CORP., ET AL.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The Federal Food, Drug, and Cosmetic Act authorizes the Food and Drug Administration (FDA) to regulate products as "drugs" or "devices" when they are "intended to affect the structure or any function of the body." 21 U.S.C. 321(g)(1)(C) and (h)(3). FDA has found that the nicotine contained in tobacco products is a highly addictive substance that causes significant mood-altering effects, and that tobacco products are intended by tobacco manufacturers to have substantial effects on the structure and functioning of the human body, including satisfying a user's addiction and acting as a sedative, stimulant, and appetite suppressant. The question presented is whether, given FDA's findings, tobacco products are subject to regulation under the Act as "drugs" and "devices."

II

PARTIES TO THE PROCEEDING

The petitioners are: Food and Drug Administration, and Jane E. Henney, Commissioner of Food and Drugs.

The respondents are: Brown and Williamson Tobacco Corp.; Lorillard Tobacco Company; Philip Morris, Incorporated; RJ Reynolds Tobacco Company; Coyne Beahm, Incorporated; National Association of Convenience Stores; ACME Retail, Incorporated; United States Tobacco Company; Conwood Company, LP; National Tobacco Company, LP; Pinkerton Tobacco Company; Swisher International, Incorporated; Central Carolina Grocers, Incorporated; J.T. Davenport, Incorporated; North Carolina Tobacco Distributors Committee, Incorporated; The American Advertising Federation; American Association of Advertising Agencies; Association of National Advertisers, Incorporated; Magazine Publishers of America; the Outdoor Advertising Association of America, Incorporated; and Point of Purchase Advertising Institute.

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PETITION FOR A WRIT OF CERTIORARI

The Solicitor General, on behalf of the Food and Drug Administration, *et al.*, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Fourth Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App. 1a-75a)¹ is reported at 153 F.3d 155. The opinion of the district court (App. 76a-136a) is reported at 966 F. Supp. 1374.

JURISDICTION

The judgment of the court of appeals was entered on August 14, 1998. A petition for rehearing was denied on November 10, 1998. App. 137a-146a. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

¹ "App." refers to the separately-bound appendix to this petition.

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The relevant provisions of the Federal Food, Drug, and Cosmetic Act and the tobacco product regulations are reproduced in the appendix to this petition. App. 148a-163a.

STATEMENT

1. This case concerns the authority of the Secretary of Health and Human Services, through the Food and Drug Administration (FDA), to regulate cigarettes and smokeless tobacco (tobacco products) as "drugs" and "devices" under the Federal Food, Drug, and Cosmetic Act (Act), ch. 675, 52 Stat. 1040, 21 U.S.C. 301 *et seq.* Before that Act was passed in 1938, the Pure Food and Drug Act defined a "drug" to include "any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals." Pure Food and Drug Act of 1906, ch. 3915, § 6, 24 Stat. 769. In the 1938 Act, Congress expanded the definition of "drug" to include "articles (other than food) intended to affect the structure or any function of the body of man or other animals." § 201, 52 Stat. 1041; see 21 U.S.C. 321(g)(1)(c). Congress also authorized FDA to regulate "device[s]." § 201, 52 Stat. 1041. The term "device" is now defined to mean, *inter alia*, "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, * * * intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. 321(h). In expanding the operative definitions in 1938, "Congress fully intended that the Act's coverage be as broad as its literal language indicates—and equally clearly, broader than any strict medical definition might otherwise allow." *United States v. Bacto-Unidisk*, 394 U.S. 784, 798 (1969).

The Act recognizes that certain products may constitute "a combination of a drug, device, or biological product." 21 U.S.C. 353(g)(1). FDA may regulate drug/device combination products using its drug authorities, device authorities, or both. 61 Fed. Reg. 44,396, 44,400-44,403 (1996) (explaining the basis for that conclusion).

The Act delegates broad authority to FDA to regulate "drugs" and "devices" for the purpose of protecting the public health. Of particular relevance here, FDA "may by regulation require that a device be restricted to sale, distribution, or use * * * upon such * * * conditions as [FDA] may prescribe in such regulation, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, [FDA] determines that there cannot otherwise be reasonable assurance of its safety and effectiveness." 21 U.S.C. 360j(e)(1). In making findings with respect to safety and effectiveness, FDA "weigh[s] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. 360c(a)(2)(C); see 21 C.F.R. 860.7(d)(1); 61 Fed. Reg. at 44,412-44,413.

2. In response to petitions filed by public health organizations requesting that FDA regulate tobacco products, FDA conducted an extensive investigation, issued a proposed rule and jurisdictional analysis, and invited public comment. 60 Fed. Reg. 41,314 (1995). In August 1996, FDA determined that tobacco products are "drugs" and "devices" under the Act and, accordingly, issued regulations directed to those products. 61 Fed. Reg. at 44,396-44,397.

FDA based its determination that tobacco products are "drugs" and "devices" on two key findings. First, based on extensive scientific documentation, FDA found that the nicotine in tobacco products "affects the structure or any function of the body" because it causes and sustains addiction, and acts as a sedative, stimulant, and appetite suppres-

sant. 61 Fed. Reg. at 44,630, 44,664-44,685. Second, FDA found that those effects are clearly "intended" by the manufacturers of tobacco products. *Id.* at 44,630, 44,686-45,204, 45,227, 45,233-45,236. The evidence before the agency included much material that was only recently uncovered through FDA's investigation, congressional hearings, and disclosures by tobacco company officials and employees.

a. In finding that nicotine affects the structure and function of the body, FDA relied on scientific evidence showing that the nicotine in tobacco products produces chemical reactions in the brain that motivate repeated, compulsive use and create dependence in the user. 61 Fed. Reg. at 44,666. In particular, nicotine directly affects a part of the brain known as the mesolimbic system, which rewards the repeated consumption of certain pleasurable substances. By increasing the activity of the neurotransmitter dopamine within that system, nicotine causes the compulsive drug-seeking behavior of drug addiction. *Id.* at 44,700. In some cases, nicotine in tobacco products acts as a sedative, while in other cases, it acts as a stimulant. *Ibid.* Clinical and animal studies also indicate that nicotine can cause weight loss. *Ibid.* FDA found that those effects on the structure and function of the body are quintessentially drug-like, identical to those FDA has found in other products that it regulates under the Act, including stimulants, tranquilizers, appetite suppressants, nicotine replacement products, and narcotics used to treat addiction (*e.g.*, methadone). *Id.* at 44,632, 44,666-44,670.

b. FDA based its conclusion that nicotine's effects on the structure and function of the body are "intended" by manufacturers on findings that: (1) a reasonable manufacturer could foresee that consumers will use tobacco products to satisfy their nicotine addiction; (2) consumers use tobacco products because they are addicted to them and because they want to obtain their mood-altering effects; (3) manufac-

turers know that consumers use tobacco products primarily for those reasons; and (4) manufacturers have carefully engineered tobacco products to deliver pharmacologically active doses of nicotine. 61 Fed. Reg. at 44,630, 44,686-45,204, 45,227, 45,233-45,236.

FDA pointed to extensive, recently-discovered evidence that supports each of those findings. For example, internal industry memoranda from the early 1970s show that R.J. Reynolds scientists regarded nicotine as a "potent" and "habit-forming" drug, considered cigarettes to be "a vehicle for delivery of nicotine," and conceived of the tobacco industry itself as "a specialized, highly ritualized and stylized segment of the pharmaceutical industry." 61 Fed. Reg. at 44,867. R.J. Reynolds researchers also recognized in the 1970s that "[t]he confirmed user of tobacco products is primarily seeking the physiological 'satisfaction' derived from nicotine," *id.* at 44,868, and that "[w]ithout any question, the desire to smoke is based on the effect of nicotine on the body," *id.* at 44,871. That knowledge was communicated to the highest levels of the tobacco companies; as early as 1969, Philip Morris's vice president for research and development notified his board of directors that "the ultimate explanation for the perpetuated cigaret[te] habit resides in the pharmacological effect of smoke upon the body of the smoker." *Id.* at 44,856.

FDA also found evidence that "[m]anufacturers of commercially marketed cigarettes commonly manipulate nicotine deliveries to provide remarkably precise, pharmacologically active doses of nicotine to consumers." 61 Fed. Reg. at 44,951. Such manufacturers use "nicotine-rich tobacco blends in low-tar cigarettes," "filtration and ventilation technologies that selectively remove more tar [than nicotine] from smoke," and "chemical additives that increase the percentage of 'free' nicotine in cigarette smoke." *Ibid.* FDA found evidence that smokeless tobacco manufacturers also

manipulate nicotine deliveries. *Id.* at 45,108. FDA quoted company documents revealing that senior industry officials and researchers expressly conceived of cigarettes and smokeless tobacco as “a dispenser for a dose unit of nicotine,” *id.* at 44,856, “a vehicle for delivery of nicotine, designed to deliver the nicotine in a generally acceptable and attractive form,” *id.* at 44,868, and the “means of providing nicotine dose in a metered fashion,” *id.* at 44,890.

c. Based on the record evidence, FDA concluded that the nicotine in tobacco products is a “drug,” 61 Fed. Reg. at 45,207, that tobacco products contain “device components” for the delivery of that drug, and that cigarettes and smokeless tobacco are “combination products.” *Id.* at 45,208-45,216.

3. a. Having concluded that tobacco products fall within its regulatory authority, FDA determined that such regulation is consistent with the agency’s mission to protect the public health because of the serious threat to public health caused by tobacco use. 61 Fed. Reg. at 44,398. The evidence in FDA’s rulemaking record shows that tobacco use is the largest cause of preventable death in the United States; more than 400,000 deaths result each year from illnesses such as cancer, respiratory illnesses, and heart disease that are caused by tobacco use. Tobacco alone kills more Americans annually than AIDS, alcohol, car accidents, homicides, suicides, illegal drugs, and fires combined. The average tobacco user loses 15 years of his or her life. *Id.* at 44,571.

FDA found that tobacco use is a “pediatric disease,” 61 Fed. Reg. at 44,421, because most people who use tobacco as adults began smoking regularly during childhood, and childhood initiation leads to addiction. Nearly all first use of tobacco occurs before high school graduation. If adolescents can be kept tobacco-free, most will never start using tobacco. *Id.* at 44,399, 44,421. Efforts to prevent childhood tobacco use, however, have not been successful thus far. Every year,

approximately one million children and adolescents begin to smoke, *id.* at 44,398, 44,568, and the rate of youth tobacco use is increasing, *id.* at 44,399. Tragically, one of every three young people who become regular smokers will eventually die prematurely from a tobacco-related disease. *Id.* at 44,399, 44,568.

b. Because of the evidence that most tobacco-related addiction begins in childhood, FDA directed its initial regulatory efforts to reducing the use of tobacco products by young people. It adopted access restrictions that: (1) prohibit the sale of cigarettes and smokeless tobacco products to persons under age 18; (2) require retailers to check the identification of persons under age 27; and (3) prohibit vending machine sales and self-service displays of cigarettes and smokeless tobacco except in adult-only locations. 61 Fed. Reg. at 44,616-44,617.

Based on evidence that “cigarette and smokeless tobacco advertising plays a material role in the decision of children and adolescents under the age of 18 to engage in tobacco use,” 61 Fed. Reg. at 44,489, and internal company documents that show the industry’s intent “to attract young smokers and so-called presmokers” through advertising, *id.* at 44,480, FDA also concluded that advertising restrictions are necessary to complement the access restrictions. *Id.* at 44,406-44,407 (“The effectiveness of the restrictions on youth access would be substantially diminished if the manufacturers were free to entice children and adolescents to circumvent the access restrictions.”). FDA’s advertising restrictions include: (1) a requirement that advertisements appear in black-and-white, text-only format, except in adult publications and adult-only facilities; (2) a ban on outdoor advertising within 1000 feet of schools and public playgrounds; (3) a prohibition on the sale or distribution by tobacco companies and distributors of hats, t-shirts, and other non-tobacco products, such as promotional items, that bear a tobacco product

brand name or logo; and (4) a prohibition on sponsoring athletic, cultural, or other events in a tobacco brand name. *Id.* at 44,617-44,618.

In adopting the complementary access and advertising restrictions, FDA invoked its authority under 21 U.S.C. 360j(e) to place conditions on the sale, distribution, and use of a device if FDA determines that "there cannot otherwise be reasonable assurance of its safety and effectiveness." FDA relied on that authority because tobacco products are "combination products" for which FDA has discretion to use its drug authorities, its device authorities, or both. 61 Fed. Reg. at 44,400-44,403.

c. FDA considered, but rejected, a ban on the sale of tobacco products to adults. FDA noted that, because of illnesses caused by cigarettes and smokeless tobacco, those products are "unsafe, as that term is conventionally understood." 61 Fed. Reg. at 44,412. But FDA further noted that, as reflected in the Act and judicial decisions construing it, the determination whether there is a "reasonable assurance of safety" within the meaning of the Act "involves consideration of not only the risks presented by a product but also any of the countervailing effects of use of that product, including the consequences of not permitting the product to be marketed." *Id.* at 44,412-44,413. For several reasons, FDA concluded that, with respect to adults, "the sudden withdrawal from the market of products to which so many millions of people are addicted would be dangerous." *Id.* at 44,413. First, "there could be significant health risks to many of these individuals." *Ibid.* Second, the health care system could be "overwhelmed by the treatment demands that these people would create, and it is unlikely that the pharmaceuticals available could successfully treat the withdrawal symptoms of many tobacco users." *Ibid.* Third, because of the strength of the addiction, and the difficulty of quitting, "a black market and smuggling would develop to

supply smokers with these products," and the black market products would likely "be even more dangerous than those currently marketed, in that they could contain even higher levels of tar, nicotine, and toxic additives." *Ibid.*

4. Respondents (tobacco companies, advertisers, and retailers) brought suit in the United States District Court for the Middle District of North Carolina, challenging the validity of FDA's regulations. Respondents moved for summary judgment, arguing that: (1) Congress has withheld from FDA any authority to regulate cigarettes and smokeless tobacco, as marketed by respondents; (2) the Act does not authorize FDA to regulate advertising of cigarettes and smokeless tobacco; and (3) the restrictions that FDA placed on advertising and promotion of cigarettes and smokeless tobacco violate the First Amendment. For purposes of its summary judgment motion, respondents accepted as true the facts found by FDA concerning the effects of tobacco products on the human body, and the intent of the manufacturers to cause those effects. App. 76a-78a.

The district court denied summary judgment to respondents on the issue of whether tobacco products are covered by the Act and the validity of the access regulations, but granted their motion with respect to the advertising regulations. App. 76a-136a. The district court first held that FDA had lawfully concluded that tobacco products are subject to regulation under the Act as "drugs" and "devices." *Id.* at 80a-126a. The court rejected respondents' contention that the Act applies only to products that have a medical purpose. The court noted (*id.* at 102a-103a & n.13) that the Act separately covers products intended for use "in the diagnosis, cure, mitigation, treatment, or prevention of disease," 21 U.S.C. 321(g)(1)(B) and (h)(2); and it explained that, because the definitions on which the FDA relied expressly include all products intended to affect the "structure or any function of the human body," the "plain language" of the Act does not

limit its reach to only those drugs and devices that have a medical purpose. See App. 113a-116a.

The district court also held that FDA had properly determined that tobacco products are "intended" to affect the structure or function of the human body within the meaning of the Act. App. 104a-113a. The court rejected respondents' contention that FDA's general regulations interpreting and implementing the Act's "intended use" standard limit evidence of intended use to explicit representations by manufacturers concerning the therapeutic or other effects of the product. The court pointed out that the regulations provide as well for consideration of consumer use and a manufacturer's knowledge of such use. See *id.* at 109a-110a & n.15 (quoting 21 C.F.R. 201.128 and 21 C.F.R. 801.4). In addition, the district court noted that a number of courts, as well as the House Report on the Medical Device Amendments of 1976 (see H.R. Rep. No. 853, 94th Cong., 2d Sess. 14 (1976)), had stated that FDA could rely on evidence other than manufacturers' representations, such as evidence of consumer use. *Id.* at 107a-108a, 110-112a.

Because it found that cigarettes and smokeless tobacco fall within the Act's definitions of "drug" and "device," the district court concluded that those products would be excluded from the Act's coverage only if respondents established that "Congress has expressed its clear intent to withhold from FDA jurisdiction to regulate tobacco products in some place other than the text of the [Act]." App. 81a. The court found no such clear intent. *Id.* at 89a-101a. In particular, it rejected respondents' contention that other statutes enacted after 1938, including the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. 1331 *et seq.*, establish a congressional intent to withhold jurisdiction from FDA to regulate tobacco products. App. 92a-101a. The court similarly rejected respondents' contention that FDA's prior decisions not to regulate most tobacco products and

statements to Congress that tobacco products were not covered by the Act unless manufacturers made therapeutic claims for them showed that Congress had withheld jurisdiction. The court explained that FDA was entitled to revisit the question in light of the new evidence concerning the addictive and other effects of tobacco products and the intended use of tobacco products to achieve those effects. *Id.* at 84a-92a.

After concluding that FDA had properly exercised jurisdiction over tobacco products, the district court held that FDA had authority under 21 U.S.C. 360j(e) to issue restrictions on access by minors to tobacco products. It therefore upheld the regulations' access restrictions. App. at 133a. Declining to reach the First Amendment issue (*id.* at 134a n.33), the district court ruled, however, that FDA's advertising restrictions are not authorized by the provision of the Act allowing FDA to impose conditions on the "sale, distribution, or use" of "devices." *Id.* at 127a-133a. The district court certified all of its rulings for interlocutory appeal, *id.* at 135a-136a, and the court of appeals accepted that certification, *id.* at 11a.²

5. a. In a 2-1 decision, a panel of the Fourth Circuit reversed, App. 1a-75a, holding that "FDA lacks jurisdiction to regulate tobacco products" and that "all of the FDA's August 28, 1996 regulations of tobacco products are thus invalid," *id.* at 11a-12a. The panel majority disagreed with the district court's framing of the issue as whether, in light of the broad definition of "drug" and "device," Congress nonetheless intended to withhold from FDA jurisdiction to regulate tobacco products. *Id.* at 15a. Rather, the majority

² In light of its rulings, the district court permitted the access restrictions prohibiting the sale of tobacco products to children under the age of 18 and the requirement for photographic identification for persons under the age of 27 to remain in effect. The court stayed implementation of the other access restrictions, which had not yet taken effect. App. 135a.

viewed the relevant question as “whether Congress intended to give the FDA jurisdiction over tobacco products as customarily marketed.” *Id.* at 14a.³ The majority noted that, under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), “the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress,” and that “only if the intent of Congress is ambiguous [do] we defer to a permissible interpretation by the agency.” App. 15a-16a. The majority also stated that “[a] precondition to deference under *Chevron* is a congressional delegation of administrative authority,” *id.* at 16a (quoting *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649 (1990)), so that “no deference is due the FDA’s construction of the Act unless it is acting within the bounds of its congressionally-established authority,” *ibid.* The majority believed that a particularly searching inquiry was necessary because FDA was “attempting to expand the scope of its jurisdiction.” *Id.* at 16a-17a.

To ascertain Congress’s intent, the majority looked first to the Act’s definitions and concluded that the plain meaning of those provisions “may appear to support the government’s position that tobacco products fit within the Act’s definitions of drugs or devices.” App. 19a. The majority concluded, however, that FDA could not rely on the definitional provisions, because, in its view, tobacco products do not fit into the overall regulatory scheme created by Congress. *Id.* at 22a.

The majority concluded that, under the provision of the Act upon which FDA had relied in issuing its regulations, 21

³ The court used the term “customarily marketed” to refer to tobacco products marketed with claims concerning smoking pleasure and the like, rather than therapeutic claims, such as weight loss. App. 14a-15a n.9. The lower courts have sustained FDA’s authority to regulate cigarette products that are marketed with express claims of therapeutic value, and respondents concede that such authority exists. See *id.* at 80a n.3.

U.S.C. 360j(e), FDA has a responsibility to determine that there is a reasonable assurance of safety of a product that it declines to ban completely from the market. App. 22a. Because FDA had found tobacco products to be dangerous, the majority concluded, “FDA cannot comply with the terms of the very statutory provision it has chosen as its basis for regulation.” *Id.* at 23a. For substantially the same reason, the majority concluded that FDA’s regulatory approach failed to satisfy several other provisions of the Act. *Id.* at 23a-30a. The majority concluded that “FDA’s need to maneuver around the obstacles created by the operative provisions of the Act reflects congressional intent not to include tobacco products within the scope of the FDA’s authority.” *Id.* at 29a-30a.

The majority also examined what it termed “extrinsic evidence” of congressional intent. App. 31a-52a. First, the majority concluded, on the basis of its review of various statements by FDA, see *id.* at 31a-37a, that “[f]rom 1914 until the present rulemaking attempt, the FDA had consistently stated that tobacco products were outside the scope of its jurisdiction.” *Id.* at 31a. The majority next concluded that Congress’s failure to enact bills that would have given FDA authority over tobacco products “provide[s] strong evidence of congressional intent that it, and not the FDA, controls the regulation of tobacco products.” *Id.* at 39a. And, it concluded that four tobacco-specific statutes enacted since 1964 provide “corroborating evidence” that Congress did not intend the FDA’s original jurisdictional grant to include “tobacco products.” *Id.* at 40a; see generally *id.* at 39a-52a.

b. Judge Hall dissented. App. 55a-75a. He concluded that “[t]obacco products fit comfortably into the [Act’s] definitions of ‘drug’ and ‘device,’” and, even if the “search for legislative intent [is expanded] beyond the words of the statute, the evidence falls far short of demonstrating that

Congress intended to deny or withdraw jurisdiction over tobacco from the FDA." *Id.* at 55a. He noted that "[t]he majority devote[d] approximately three paragraphs to the words that form the heart of the FDA's jurisdictional claim" and essentially "conced[ed] that tobacco products fit the [Act's] 'literal' definition of drug." *Id.* at 56a.

Judge Hall rejected the majority's view that, since FDA has a mandate to prevent the marketing of a drug found to be unsafe and tobacco products are unsafe, the regulations at issue must be inconsistent with that mandate, because they do not ban the continued sale of tobacco products to adults. App. 60a-61a. He concluded that "[h]ow the FDA has chosen to regulate tobacco has no bearing on the question of *whether* that agency has the authority to regulate it at all. * * * It is no argument to say that the FDA can do nothing because it could have done more." *Ibid.*

Judge Hall also concluded that "[t]he majority starts off on the wrong foot when it asks 'whether Congress intended to delegate jurisdiction over tobacco products to the FDA,'" because "Congress did not 'intend' that any particular product be included." App. 62a. Rather, "[t]he operative congressional intent * * * was simply to confer broad discretionary powers on the FDA to regulate 'drugs' and 'devices'" through definitions that were "written broadly enough to accommodate both new products and evolving knowledge about existing ones." *Id.* at 63a.

Judge Hall similarly disagreed with the majority's reliance on FDA's prior decisions and statements regarding the regulation of tobacco products. App. 63a. He pointed out that "an agency can change its view of what action is possible or necessary, particularly when new facts come to light." *Id.* at 64a. Here, he explained, FDA had a strong basis for changing its position because of new evidence that "nicotine is extremely addictive and that a large majority of tobacco users use the product to satisfy that addiction," and,

even more important, because of new evidence that "manufacturers design their products to sustain such addiction." *Id.* at 65a. Finally, Judge Hall concluded that the tobacco-specific statutes cited by the majority address narrow subjects and fall far short of showing that Congress intended to prevent FDA from exercising jurisdiction over tobacco products. *Id.* at 65a-70a.⁴

The Fourth Circuit denied FDA's petition for rehearing. App. 137a-146a. Judge Hall would have granted panel rehearing, and Judges Michael, Motz, and Murnaghan would have granted rehearing en banc. *Id.* at 145a-146a. Four active judges were disqualified from the case. *Id.* at 146a.

REASONS FOR GRANTING THE PETITION

A divided court of appeals has ruled that FDA has no authority to regulate tobacco products, and it has invalidated the most important public health and safety rulemaking that FDA has conducted in the past fifty years. The panel reached that conclusion notwithstanding FDA's thoroughly documented findings, based on extensive evidence in the record, that the nicotine in tobacco products is intended to cause substantial effects on the human body, including satisfying a user's addiction and acting as a sedative, stimulant, and appetite suppressant.

The panel's ruling is based on a fundamentally flawed approach to the interpretation of the Federal Food, Drug, and Cosmetic Act, and it drifts far afield from the kind of analysis of administrative action required by this Court's decision in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Unless reversed by this Court, the panel's ruling will deprive the public of an unparalleled opportunity to prevent millions of children from

⁴ Judge Hall also concluded that FDA has authority to regulate tobacco products as "combination product[s]" and to restrict tobacco product advertising under its "device" authority. App. 71a-74a.

beginning a highly addictive habit that often leads to premature death. FDA regulations currently in effect, but invalidated by the court of appeals, are already restricting youth access to tobacco products. The public health suffers in a substantial way as each month passes and FDA's other tobacco product regulations relating to access and advertising remain blocked by court order. The recent agreement between five tobacco companies and 46 States settling financial claims by the States to compensate them for the health-care costs of tobacco use (see note 9, *infra*), does not diminish the public health significance of FDA's regulatory program. To the contrary, it vividly confirms the serious public health consequences of tobacco use. Review by this Court is therefore warranted to resolve the question whether, given FDA's thoroughly documented findings about the intended pharmacological effects of tobacco products on the human body, tobacco products are "drugs" and "devices" covered by the Act.

A. The panel majority in this case held that "FDA lacks jurisdiction to regulate tobacco products." App. 11a-12a. Under that ruling, unless tobacco manufacturers market their products with "specific therapeutic claims such as weight loss," *id.* at 15a n.9, FDA is completely without authority over such products. The panel's holding is based on a serious misreading of the Act and a fundamental misapplication of basic administrative law principles.

1. The Act sets forth a standard for whether a product is subject to regulation as a "drug." That standard is uniformly applicable to all products not expressly exempted. It provides that the term "drug" not only includes "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," but also includes, *inter alia*, "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. 321(g)(1). The Act similarly sets forth a standard for

whether a product is a "device" that is uniformly applicable to all products not expressly exempted. The Act provides that a "device" is, *inter alia*, "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, * * * intended to affect the structure or any function of the body of man or other animals * * * and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. 321(h).

This Court has held that "Congress fully intended that the Act's coverage be as broad as its literal language indicates—and equally clearly, broader than any strict medical definition might otherwise allow." *United States v. Bacto-Unidisk*, 394 U.S. 784, 798 (1969). Moreover, while the Act specifically excludes certain products from particular product categories—soap is excluded from the definition of "cosmetic," 21 U.S.C. 321(i), and tobacco itself is excluded from the definition of "dietary supplement," 21 U.S.C. 321(ff)(1)—the Act does not exclude tobacco products from the definition of "drug" or "device." Thus, tobacco products, like all other products containing nicotine, are subject to regulation under the Act if they are "intended to affect the structure or any function of the body." 21 U.S.C. 321(g)(1) and (h).

Applying that statutory standard, FDA concluded that tobacco products fall within the statutory standards for both "drug" and "device." FDA's conclusion is based on an overwhelming factual record showing that: (1) the nicotine in tobacco products causes and sustains addiction, and acts as a sedative, stimulant, and appetite suppressant; (2) most persons who use tobacco products do so in order to achieve those effects; (3) tobacco manufacturers know that consumers use their products for those purposes; and (4) tobacco manufacturers design their products to deliver pharmacologically active doses of nicotine. Given that evidence, FDA

reasonably concluded that tobacco products are “intended” to “affect the structure or any function of the body” and are, therefore, subject to regulation under the Act. 21 U.S.C. 321(g)(1) and (h).

Indeed, it is difficult to see how FDA could have come to a different conclusion based on the record before it. As FDA pointed out, in light of its findings, tobacco products cannot be distinguished meaningfully from other products that FDA regulates, such as stimulants, tranquilizers, appetite suppressants, nicotine replacement products, and narcotics used to treat addiction. 61 Fed. Reg. at 44,632, 44,666-44,670.

It is not necessary for present purposes, however, for the Court to decide whether the text of the Act, as applied to the evidence in the rulemaking record, *compels* the conclusion that tobacco products are “drugs” and “devices” subject to regulation under the Act. Congress assigned to FDA the responsibility to implement the statutory scheme by determining which products satisfy the statutory standards in light of the evidence pertaining to each particular product. Accordingly, FDA’s interpretation and application of the complex statutory framework at issue in this case lies at the very core of agency action that is entitled to deference under *Chevron*, 467 U.S. at 842-845. That means that “a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.” *Id.* at 844. At the very least, in view of FDA’s thoroughly documented findings, FDA reached the “reasonable” conclusion that tobacco products fall within the coverage of the Act. The panel majority was therefore required by *Chevron* to defer to FDA’s conclusion.⁵

⁵ A different conclusion could be reached only if an express market claim were the sole ground on which FDA could determine the intended use of a product. Under that interpretation of the Act, tobacco products would be subject to regulation only if manufacturers made specific market claims that their products satisfy addiction, and act as a stimulant, seda-

2. The court of appeals’ holding that FDA lacks authority to regulate tobacco products, notwithstanding the plain statutory text and compelling factual record before FDA, rests on a series of legal errors. Those errors fall into three categories.

a. First, the panel started with the wrong question when it asked “whether Congress intended to give the FDA jurisdiction over tobacco products.” App. 15a. As Judge Hall noted in dissent, “Congress did not ‘intend’ that any particular product be included.” *Id.* at 62a. Instead, it enacted general definitions of “drug” and “device” so that FDA—applying its accumulated scientific and administrative expertise to both newly developed products and expanded medical knowledge concerning existing products—could decide whether a particular product is subject to regulation based on the evidence before it. *Id.* at 62a-63a. Accordingly, the relevant question in this case is not whether Congress in-

tive, and appetite suppressant. As FDA found, however, the text of the Act provides no basis for imposing such a market-claim limitation; it makes “intended uses,” not “market claims” or “manufacturer representations,” the decisive factor. See 21 C.F.R. 201.128 (describing the evidence relevant to determining intent for drug products); 21 C.F.R. 801.4 (equivalent provision for devices). An express market claim is one important source of evidence concerning intended use. But, as the present case demonstrates, an intended use can be established through other means. From a public health perspective, moreover, it would make no sense to conclude that tobacco products are subject to regulation when manufacturers make specific market claims that their products satisfy addiction and act as stimulants and sedatives, but are not subject to regulation when manufacturers, knowing that consumers use their products for those purposes, engineer their products in order to produce those effects but refrain from making express market claims. At the very least, FDA’s judgment that the Act allows intent to be established on the basis of evidence other than express market claims is reasonable and therefore entitled to *Chevron* deference. Significantly, the court of appeals in this case did not hold that FDA could rely only on market claims in determining the intended use of products. App. 19a-20a.

tended to delegate authority to FDA over tobacco products in particular or in the abstract, but whether Congress intended to delegate authority to FDA to regulate tobacco products (along with any other products not expressly exempted) in the event that FDA found that they are "intended to affect the structure or any function of the body." 21 U.S.C. 321(g)(1) and (h). The answer to that question is clearly yes, since that is the standard that Congress established, and Congress did not exempt tobacco products from review under that standard.

Once the question is correctly posed, moreover, it is evident that the court of appeals seriously erred in basing its conclusion that FDA lacks jurisdiction over tobacco products on (i) its own view that the Act lacks regulatory provisions that are appropriate for tobacco products, (ii) unenacted bills proposed after 1938 that would have given FDA authority to regulate tobacco products, and (iii) tobacco-specific laws enacted since 1964 that address different issues. Those materials do not provide a principled basis on which to hold that Congress intended to prevent FDA from regulating tobacco products altogether should it find, based on compelling evidence of the sort before FDA in 1996, that tobacco products are intended to affect the structure or any function of the body.⁶

b. Second, the court of appeals' decision rests on fundamental misconceptions concerning *Chevron* deference. The court of appeals stated that "[a] precondition to deference under *Chevron* is a congressional delegation of administrative authority," App. 16a (quoting *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649 (1990)), so that "no deference is due the FDA's construction of the Act unless it is acting

⁶ Furthermore, as we explain in greater detail below (see pp. 22-27, *infra*), those justifications offered by the court of appeals for its contrary holding are without merit even on their own terms.

within the bounds of its congressionally-established authority," App. 16a. That statement implies that, before applying the analysis required by *Chevron* to the question whether FDA has authority over tobacco products, a court must first determine independently whether Congress has delegated to FDA the authority to regulate tobacco products. That approach is circular and would drain *Chevron* of any meaning. The holding in *Adams Fruit*, that a precondition to deference under *Chevron* is a "congressional delegation of administrative authority," simply means that Congress must have delegated authority to the agency to enforce the statutory provision whose meaning is at issue. *Adams Fruit*, 494 U.S. at 650; *Chevron*, 467 U.S. at 842-845. Here, Congress has clearly delegated authority to FDA to enforce provisions of the Act that depend on the meaning of the terms "drug" and "device." FDA therefore is unquestionably entitled to *Chevron* deference on the meaning and scope of those terms.

Adams Fruit, on which the majority below relied, addressed a completely different situation. The question in that case was whether state workers' compensation laws bar private rights of action under the Migrant and Seasonal Agricultural Worker Protection Act, 29 U.S.C. 1801 *et seq.* The Court declined to give deference to a regulation of the Department of Labor on that question because the private right of action was administered by the courts and not by the Department of Labor. The Court explained that, because Congress had established "an enforcement scheme independent of the Executive and provided aggrieved farmworkers with direct recourse to federal court where their rights under the statute are violated[,] * * * it would be inappropriate to consult executive interpretations * * * to resolve ambiguities surrounding the scope of [the] judicially enforceable remedy." 494 U.S. at 650. Since the question presented here involves the scope of FDA's authority under

the very law Congress directed it to administer, *Adams Fruit* is inapposite here.

The court of appeals' analysis of the issue under *Chevron* was also affected by its characterization of FDA's action as "attempting to expand the scope of its jurisdiction." App. 16a. As long as an agency is reasonably interpreting a provision it enforces, however, *Chevron* deference applies. It is simply not relevant whether the agency's proposed interpretation can be said to affect its jurisdiction. *Commodity Futures Trading Comm'n v. Schor*, 478 U.S. 833, 844-845 (1986); *NLRB v. City Disposal Sys., Inc.*, 465 U.S. 822, 830 n.7 (1984); see also *Mississippi Power & Light Co. v. Mississippi ex rel. Moore*, 487 U.S. 354, 380-382 (1988) (Scalia, J., concurring) (collecting cases). A contrary rule of interpretation would be unworkable, for *Chevron* deference would then be rendered of little or no force whenever FDA sought to regulate any of the vast range of food and drug products that are introduced each year.

The panel's holding in this case thus cannot be reconciled with a proper application of *Chevron*. In light of FDA's findings concerning the intended effects of tobacco products, and the plain language of the only directly relevant provisions of the Act—the "drug" and "device" definitions—FDA acted reasonably in concluding that tobacco products are subject to regulation under the Act.

c. Third, to the extent that the court of appeals concluded that Congress clearly intended to preclude FDA from regulating tobacco products, that conclusion conflicts with the plain language of the controlling definitions of "drug" and "device." It also ignores the absence of any exemption from those definitions for tobacco products, an absence made all the more telling by Congress's decision to enact an express exemption for tobacco from the Act's definition of "dietary supplement." See 21 U.S.C. 321(ff)(1). And, as we shall now

explain, the panel's conclusion is also unsupported by the materials upon which it relied.

The panel concluded that, because FDA found tobacco products to be dangerous, it would be required by 21 U.S.C. 360j(e) to prohibit the sale of tobacco products to adults as well as children if those products are covered by the Act. App. 21a-23a. For that reason, the panel believed, FDA "cannot comply with the terms of the very statutory provision it has chosen as its basis for regulation." *Id.* at 23a. The Act, however, does not require FDA to consider only the risks of tobacco products. Instead, the Act and implementing regulations authorize FDA to weigh the health risks of permitting continued sales of tobacco products to adults against the health risks of prohibiting such sales. 61 Fed. Reg. at 44,412-44,413 (discussing 21 U.S.C. 360c(a)(2)(C) and 21 C.F.R. 860.7(d)(1)). After engaging in that weighing process, FDA concluded that, with respect to adults, "[t]he sudden withdrawal from the market of products to which so many millions of people are addicted would be dangerous." *Id.* at 44,413. That public health policy conclusion was well-founded, and the panel majority should not have second-guessed it. As FDA found, prohibiting adult access to tobacco products "could [create] significant health risks" for persons addicted to such products. 61 Fed. Reg. at 44,413. The health care system could be "overwhelmed by the treatment demands that these people would create, and it is unlikely that the pharmaceuticals available could successfully treat the withdrawal symptoms of many tobacco users." *Ibid.* Equally important, because of the strength of nicotine addiction, and the difficulty of quitting, "a black market and smuggling would develop to supply smokers with these products," and it is likely that those products "would be even more dangerous than those currently marketed, in that they could contain even higher levels of tar, nicotine, and toxic additives." *Ibid.* In deciding upon its

regulatory approach, FDA properly took those serious health risks into account.

At the very least, FDA's regulatory approach under 21 U.S.C. 360j(e) is reasonable, and it therefore should have been sustained under *Chevron*. But the panel majority did not even consider the question of *Chevron* deference when it rejected FDA's decision to allow continued sales to adults once FDA concluded that tobacco products are subject to regulation under the Act. See App. 21a-22a. In any event, as Judge Hall pointed out in dissent, "[h]ow the FDA has chosen to regulate tobacco has no bearing on the question of whether that agency has the authority to regulate it at all[.] It is no argument to say that the FDA can do nothing because it could have done more." *Id.* at 60a-61a (emphasis omitted).⁷

The panel majority also relied on prior statements by FDA that it did not have jurisdiction to regulate tobacco products unless manufacturers made therapeutic claims about the products' effect on the body. App. 32a-37a. That reliance was misplaced both as a matter of fact and as a matter of law. In the first place, the court of appeals was simply wrong in regarding the 1996 regulations as an abrupt change from a consistent prior position that tobacco products would be subject to regulation under the Act only if manufacturers made express health or therapeutic claims in marketing them. That notion is refuted by FDA's most recent rejection of a petition to regulate tobacco products

⁷ The panel majority's belief that there were other "internal inconsistencies" (App. 23a) in FDA's approach under the Act stemmed directly from its basic disagreement with FDA's consideration of the substantial personal and public health risks that would be caused by a complete ban on the sale of all tobacco products. On each of those subsidiary points, moreover, the court once again failed even to advert to its duty to accord *Chevron* deference to FDA's reasonable interpretation of the particular statutory provisions involved. See App. 23a-30a.

prior to 1996—the petition filed by Action on Smoking and Health (ASH) in 1978. In response to ASH's request that FDA regulate filtered cigarettes as devices because they were intended to mitigate disease, the Commissioner stated:

ASH asserts that objective evidence other than manufacturers' claims can be material to a determination of intended use under the statutory definition * * *. We agree. However, * * * ASH has not established that consumers use attached cigarette filters * * * to the extent necessary to allow FDA to impute the requisite intended uses to manufacturers or vendors.

Letter from FDA Commissioner Goyan to ASH Executive Director Banzhaf 8-9 (Nov. 25, 1980) (reprinted in 61 Fed. Reg. at 45,224) (emphasis added). In addition, as Judge Hall explained, an agency is always free to change its view on an issue, and that is particularly true "when new facts come to light." App. 64a. See *Rust v. Sullivan*, 500 U.S. 173, 186-187 (1991) (recognizing legitimacy of agency change of position). Indeed, the District of Columbia Circuit made that very point in sustaining FDA's denial of an earlier petition filed by ASH in 1977, making clear that FDA "is clearly free to revise its interpretations" if it "provide[s] a reasoned explanation for its action." *Action on Smoking & Health v. Harris*, 655 F.2d 236, 242 n.10 (1980). Significantly, the D.C. Circuit also made it clear that manufacturers' claims are *not* the only basis on which intended use of cigarettes could be established and that consumer use of a product *can* be a relevant factor in determining its intended use. See *id.* at 239-240.⁸

⁸ It is also significant that the D.C. Circuit specifically noted that it did not understand the Commissioner's rejection of ASH's 1977 petition to mean that he would consider only manufacturer representations and would decline to consider evidence of consumer intent. 655 F.2d at 239.

Prior to the present proceeding, FDA simply did not have clear and compelling evidence that nicotine is extremely addictive, that consumers use tobacco products because they are addicted to the products and want to obtain their mood-altering and other effects, that manufacturers know that consumers use tobacco products primarily for those reasons, and that manufacturers have deliberately and carefully engineered tobacco products to deliver pharmacologically active doses of nicotine. 61 Fed. Reg. at 44,630, 44,686-45,204, 45,227, 45,233-45,236; see also App. 65a. As Judge Hall noted, "[t]he administrative record in this case is a perfect illustration of why an agency's opportunity to adopt a new position should remain open." App. 65a.

The court of appeals also deemed it significant that Congress did not enact certain proposed bills that would have specifically given FDA authority to regulate tobacco products. App. 37a-40a. Failed legislative proposals, however, do not furnish a sound basis for determining the meaning of a prior statute. *Central Bank of Denver v. First Interstate Bank of Denver*, 511 U.S. 164, 187 (1994); *United States v. Estate of Romani*, 118 S. Ct. 1478, 1487-1488 (1998); *id.* at 1488-1489 (Scalia, J., concurring in part and concurring in the judgment). The Constitution requires Congress to express its will through enacted bills, not through unenacted ones. *INS v. Chadha*, 462 U.S. 919, 945-959 (1983). Congressional inaction also "lacks persuasive significance because several equally tenable inferences may be drawn from such inaction, including the inference that the existing legislation already incorporated the offered change." *Central Bank*, 511 U.S. at 187. In any event, such post-enactment inaction in the Legislative Branch cannot undermine the respect owed an agency's reasonable interpretation of the statute under *Chevron*. The court of appeals therefore erred in relying on unenacted bills here.

Finally, the panel majority relied on "tobacco-specific" legislation, such as the Federal Cigarette Labeling and Advertising Act (Labeling Act), 15 U.S.C. 1331 *et seq.*, the Comprehensive Smokeless Tobacco Health Education Act of 1986, 15 U.S.C. 4401 *et seq.*, and the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act, Pub. L. No. 92-321, 106 Stat. 394, 42 U.S.C. 300x-26. App. 40a-53a. Those Acts all address narrow issues, such as what warning labels must be put on tobacco products. See *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992) (narrowly construing the preemptive force of the Labeling Act). They do not come close to instructing FDA to refrain from *any* regulation of tobacco products even if it finds, based on compelling evidence of the sort before it in 1996, that tobacco products are intended to affect the structure or any function of the body. The suggestion by the court below (App. 44a) that those Acts show that "Congress has reserved for itself the regulation of tobacco products, rather than delegating that regulation to the FDA," is perplexing. The only way for Congress to accomplish that result would be by passing a law that repealed FDA's authority under the Federal Food, Drug, and Cosmetic Act with respect to tobacco products. And even the panel majority did not suggest that the "tobacco-specific" laws it cited did that. *Id.* at 40a, 44a.

d. In sum, when the standard that Congress has selected for determining whether a product is a drug or a device is applied to the extensive evidence before FDA, it is clear that FDA acted reasonably in concluding that tobacco products are subject to regulation under the Act as "drugs" and "devices." This Court should grant certiorari to review the panel's contrary conclusion.

B. The question presented in this case is of urgent public importance. FDA has determined that most persons who become addicted to tobacco products begin using those products when they are children, and youth tobacco use has

been on the rise. Every year, approximately one million children and adolescents begin to smoke, and one out of every three such persons will eventually die prematurely from a tobacco-related disease. 61 Fed. Reg. at 44,568. FDA's regulatory program is aimed at reversing that trend by preventing minors from beginning to use tobacco products. *Id.* at 44,399. Specifically, FDA's program is designed "to ensure that children and adolescents are unable to have access to cigarettes and smokeless tobacco," and "to prevent advertising by the manufacturers of cigarettes and smokeless tobacco from undercutting the access restrictions." *Id.* at 44,406. Unless this Court grants review, an unparalleled opportunity to curb tobacco use by children and to reduce the disease and death associated with such use will be lost.

As much promise as the current regulatory program holds, the significance of this case extends well beyond that particular program. The court of appeals not only has invalidated the current program; it has held that FDA may not issue *any* regulations with respect to tobacco products as currently marketed. For example, even if FDA determined that a particular tobacco ingredient resulted in health hazards not previously known or associated with tobacco use, or that a particular kind of filter would significantly reduce the health risks associated with cigarette use, FDA would lack authority to take action to mandate product modifications. Under the court of appeals' decision, FDA is powerless to adopt any measures designed to reduce the health risks associated with tobacco products as currently marketed, no matter how efficacious such measures might be.

The public has a vital interest in obtaining a resolution by this Court of the question whether FDA has authority to regulate tobacco products. The present case involves all major participants in the industry, including manufacturers, advertisers, and retailers; there will be no better vehicle for

resolving the issue. The parties below thoroughly canvassed the relevant legal sources, and the three opinions below (the panel majority opinion, Judge Hall's dissent, and the district court opinion) fairly stake out the two sides.

FDA regards the question of statutory authority presented in this case as one of the most important questions it has faced since the enactment of the Federal Food, Drug, and Cosmetic Act in 1938. Because the court below incorrectly resolved the issue, and because that issue is of overriding public importance, this Court's review is warranted.⁹

⁹ The recent agreement between the Nation's five largest tobacco companies and 46 States settling financial claims by the States does not affect the importance of the question presented in this case. To the contrary, the very magnitude of the payments to be made by the manufacturers confirms the serious health consequences of tobacco use. Moreover, the agreement is designed primarily to compensate States for the health-care costs incurred as a result of tobacco use; it is not a public-health measure as such. There are some restrictions on advertising included in the agreement. Because the agreement is concerned primarily with financial compensation rather than public health, however, it includes as private signatories only five tobacco manufacturers, not the thousands of other entities involved in the distribution and sale of tobacco products; it does not contain comprehensive measures to limit youth access to tobacco products; it does not comprehensively address forms and aspects of advertising that are particularly effective in enticing children to begin tobacco use; it does not contain enforcement mechanisms beyond actions by individual States to enforce the agreement; it does not contain any provision regarding manufacturing practices or review and disclosure of ingredients; and it does not reserve for the States the option to seek additional civil relief from the companies. Thus, while the agreement serves important purposes, it does not serve—and was not intended to serve—as a mechanism for protecting the public health through comprehensive nationwide regulation of tobacco products. (For the terms of the agreement, see National Association of Attorneys General, *Master Settlement Agreement* (visited Jan. 19, 1998) <http://www.naag.org/tob2.htm>).

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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No.

OFFICE OF THE CLERK

In the Supreme Court of the United States

OCTOBER TERM, 1998

FOOD AND DRUG ADMINISTRATION, ET AL., PETITIONER

v.

BROWN AND WILLIAMSON TOBACCO CORP., ET AL.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

**APPENDIX TO
PETITION FOR A WRIT OF CERTIORARI**

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APPENDIX A

**IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT**

**Nos. 97-1604, 97-1581, 97-1606,
97-1614 and 97-1605**

**BROWN & WILLIAMSON TOBACCO CORPORATION;
LORILLARD TOBACCO COMPANY; PHILIP MORRIS,
INCORPORATED; RJ REYNOLDS TOBACCO COMPANY,
PLAINTIFFS-APPELLANTS**

AND

**COYNE BEAHM, INCORPORATED;
LIGGETT GROUP, INCORPORATED, PLAINTIFFS**

v.

**FOOD & DRUG ADMINISTRATION;
DAVID A. KESSLER, M.D., COMMISSIONER OF FOOD AND
DRUGS, DEFENDANTS-APPELLEES**

**ATTORNEYS GENERAL OF THE STATE OF MINNESOTA;
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STATE OF MAINE; STATE OF MARYLAND;
STATE OF MASSACHUSETTS; STATE OF MICHIGAN;
STATE OF MISSISSIPPI; STATE OF MISSOURI;
STATE OF MONTANA; STATE OF NEVADA;
STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY;**

STATE OF NEW MEXICO; STATE OF NEW YORK;
 STATE OF NORTH DAKOTA; STATE OF OHIO;
 STATE OF OKLAHOMA; STATE OF OREGON;
 STATE OF PENNSYLVANIA; STATE OF RHODE ISLAND;
 STATE OF SOUTH DAKOTA; STATE OF TEXAS;
 STATE OF UTAH; STATE OF VERMONT;
 STATE OF WASHINGTON; STATE OF WEST VIRGINIA;
 STATE OF WISCONSIN; THE CITY AND COUNTY OF
 SAN FRANCISCO; PUBLIC CITIZEN; THE AMERICAN
 ACADEMY OF PEDIATRICS; AMERICAN CANCER
 SOCIETY; AMERICAN COLLEGE OF PREVENTIVE
 MEDICINE; AMERICAN HEART ASSOCIATION;
 AMERICAN LUNG ASSOCIATION; AMERICAN MEDICAL
 ASSOCIATION; AMERICAN MEDICAL WOMEN'S
 ASSOCIATION; AMERICAN PUBLIC HEALTH
 ASSOCIATION; AMERICAN SOCIETY OF ADDICTION
 MEDICINE; THE HMO GROUP;
 NATIONAL ASSOCIATION OF ELEMENTARY SCHOOL
 PRINCIPALS; NATIONAL ASSOCIATION OF
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 KENTUCKY; WASHINGTON LEGAL FOUNDATION
 ("WLF"); MARIO ANDRETTI; DON GARLITS; AL UNSER;
 RUSTY WALLACE; CALE YARBOROUGH; RICHARD
 BURR, CASS BALLENGER, HOWARD COBLE, UNITED
 STATES REPRESENTATIVES, LAUCH FAIRCLOTH,
 UNITED STATES SENATOR, AMICI CURIAE

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 WILLIAMSON TOBACCO CORPORATION; PHILIP MORRIS,
 INCORPORATED; RJREYNOLDS TOBACCO COMPANY;
 NATIONAL ASSOCIATION OF CONVENIENCE STORES;
 ACME RETAIL, INCORPORATED; UNITED STATES
 TOBACCO COMPANY; CONWOOD COMPANY, LP;
 NATIONAL TOBACCO COMPANY, LP; PINKERTON
 TOBACCO COMPANY; SWISHER INTERNATIONAL,
 INCORPORATED; CENTRAL CAROLINA GROCERS,

INCORPORATED; J.T. DAVENPORT, INCORPORATED;
 NORTH CAROLINA TOBACCO DISTRIBUTORS
 COMMITTEE, INCORPORATED; THE AMERICAN
 ADVERTISING FEDERATION; AMERICAN ASSOCIATION
 OF ADVERTISING AGENCIES; ASSOCIATION OF
 NATIONAL ADVERTISERS, INCORPORATED;
 MAGAZINE PUBLISHERS OF AMERICA; THE OUTDOOR
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 INCORPORATED; POINT OF PURCHASE ADVERTISING
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AND

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 DON GARLITS; AL UNSER; RUSTY WALLACE;
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NATIONAL ASSOCIATION OF CONVENIENCE STORES; ACME RETAIL, INCORPORATED, PLAINTIFFS-APPELLANTS

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[Argued: June 9, 1998
Decided: Aug. 14, 1998]

Before: WIDENER, Circuit Judge, HALL, Senior Circuit Judge, and MICHAEL, Senior United States District Judge for the Western District of Virginia, sitting by designation.

Reversed by published opinion. Judge WIDENER wrote the opinion, in which Senior Judge MICHAEL joined. Senior Judge K.K. HALL wrote a dissenting opinion.

WIDENER, Circuit Judge:

On August 28, 1996, the Food and Drug Administration (FDA) published a final rule entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents." 61 Fed.Reg. 44,396 (1996) (to be codified at 21 C.F.R. pt. 801, *et al.*). In general, this rule set out regulations restricting the sale and distribution of cigarettes and smokeless tobacco (collectively referred to as tobacco products) to minors and limiting the advertising and promotion of tobacco products. Plaintiffs (cigarette and smokeless tobacco manufacturers, convenience store retailers, and advertisers) filed these consolidated actions in federal district court, challenging the FDA's jurisdiction over tobacco products and seeking declaratory and injunctive relief.¹ Plaintiffs then filed a motion for summary judgment in the district court, alleging that, as a matter of law: (1) Congress has withheld from the FDA the jurisdiction to regulate tobacco products as marketed by plaintiffs; and (2) the Federal Food, Drug, and Cosmetic Act (Act) does not permit the FDA to regulate tobacco products either as drugs or as devices. In denying plaintiffs' motion for summary judgment in part and granting the motion in part, the district court held that Congress did

¹ When the complaint was filed on August 10, 1995, the FDA had only issued a Notice of Proposed Rulemaking. 60 Fed.Reg. 41,314 (1995). Following a comment period, the FDA adopted the proposed rule in modified form. 61 Fed.Reg. 44,396 (1996). Unless noted otherwise, all references in this opinion are to the final version of the rule published in the Federal Register on August 28, 1996. Where italics appear here within a quotation, they have been added for emphasis unless otherwise indicated.

not "[intend] to withhold from FDA" the jurisdiction to regulate tobacco products. *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1388 (M.D.N.C.1997). The district court also concluded that the FDA had authority to regulate tobacco products under the device provision of the Act, but disapproved the FDA's restrictions on advertising as inconsistent with its statutory authority. *Coyne Beahm*, 966 F. Supp. at 1393-1400. Finally, the district court stayed implementation of the majority of the FDA's regulations pending appeal.² *Coyne Beahm*, 966 F. Supp. at 1400-01. The district court certified its order for immediate interlocutory appeal pursuant to 28 U.S.C. § 1292(b), *Coyne Beahm*, 966 F. Supp. at 1401, and by order dated May 13, 1997, this court granted the § 1292(b) petitions for immediate appeal filed by two of the plaintiff groups and the FDA. In addition, the FDA had filed its Notice of Appeal dated May 2, 1997 from the partial injunction granted by the district court. Jurisdiction over the consolidated appeals is proper in this court under 28 U.S.C. §§ 1292(a)(1) and 1292(b).

Because this case arises from a motion for summary judgment, we review the judgment of the district court *de novo*. *Myers v. Finkle*, 950 F.2d 165, 167 (4th Cir.1991). For purposes of these appeals, plaintiffs do not dispute the factual findings of the FDA. Based on our review of the record and the relevant legal authorities, we are of opinion that the FDA lacks jurisdiction

² The district court left in place the FDA's proof of age requirement for tobacco sales and the restrictions on sales to persons under age 18, which had already gone into effect. *Coyne Beahm*, 966 F. Supp. at 1400. However, all 50 States have already banned the sale of tobacco to minors under state law. See 61 Fed. Reg. at 44,419 (citing a joint letter from 25 state attorneys general and other comments submitted to the FDA).

to regulate tobacco products. For the reasons set forth below, all of the FDA's August 28, 1996 regulations of tobacco products are thus invalid. Accordingly, we reverse the judgment of the district court.

I. FDA's Asserted Basis for Jurisdiction

The FDA³ has authority to regulate products only if they fall within one of the categories defined by Congress in the Act.⁴ In the jurisdictional determination attached to its August 28, 1996 regulations, the FDA asserted jurisdiction over tobacco products under the drug⁵ and device⁶ definitions in the Act. 61 Fed. Reg. at 44,628. According to the FDA, tobacco products fit within these definitions because they are "intended to affect the structure or any function of the

³ On most occasions, the Act refers to the authority of the Secretary of the Department Health and Human Services (HHS) to take certain actions. However, the Secretary acts through the Commissioner of Food and Drugs. 21 U.S.C. § 393(d)(2). For simplicity, we will refer to any legislative delegation as if made directly to the FDA.

⁴ The categories of products subject to regulation by the FDA are food, drugs, devices, and cosmetics. 21 U.S.C. § 321.

⁵ The Act defines "drug" in pertinent part as "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1)(C).

⁶ In relevant part, "device" is defined as an article which is:

intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes

21 U.S.C. § 321(h)(3).

body." More specifically, the FDA concluded that tobacco products are "combination products consisting of nicotine, a drug that causes addiction and other significant pharmacological effects on the human body, and device components that deliver nicotine to the body."⁷ 61 Fed. Reg. at 44,628, 44,649-650. Based on its classification of tobacco products as combination products, the FDA claimed that it could exercise its discretion in deciding whether the drug provisions or device provisions of the Act should apply. 61 Fed. Reg. at 44,400. Although finding that tobacco products function primarily as drugs, 61 Fed. Reg. at 45,209-218, the FDA concluded that tobacco products are most properly regulated under the device provisions of the Act, in particular the restricted devices section, 21 U.S.C. § 360j(e).⁸ 61 Fed. Reg. at 44,400. The FDA's

⁷ A combination product is described as a product that contains a combination of a drug, device, or biological product. 21 U.S.C. § 353(g). Neither party contends that tobacco products contain any "biological product," as that term is used in the Act. See 42 U.S.C. § 262(I) (defining a biological product as a "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings").

⁸ Section 360j(e) provides in relevant part:

(1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use—

. . .

(B) upon such other conditions as the Secretary may prescribe in such regulation, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.

jurisdictional determination encompasses over 600 pages in the Federal Register; however, its basic premise can be fairly summarized in one sentence. That is, the FDA asserted jurisdiction over tobacco products based on its conclusion that tobacco products fit within the literal definitions of drug and device as set forth in the Act. In short, the FDA's inquiry began and ended with the definitions section of the Act.

We are of opinion that the FDA's limited, mechanistic inquiry is insufficient to determine Congress' intent. Therefore, as directed by *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 104 S. Ct. 2778, 81 L.Ed.2d 694 (1984), we employ the traditional tools of statutory construction to ascertain congressional intent regarding whether the FDA has authority to regulate tobacco products.

II. Jurisdictional Analysis

We begin with the basic proposition that agency power is "not the power to make law. Rather, it is 'the power to adopt regulations to carry into effect the will of Congress as expressed by the statute.'" *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 213-14, 96 S. Ct. 1375, 47 L.Ed.2d 668 (1976) (quoting *Manhattan Gen. Equip. Co. v. Commission*, 297 U.S. 129, 134, 56 S. Ct. 397, 80 L.Ed. 528 (1936)). Thus, our initial inquiry is whether Congress intended to delegate to the FDA authority to regulate tobacco products as "customarily marketed."⁹

21 U.S.C. § 360j(e).

⁹ Plaintiffs use the term "customarily marketed" in their briefs to indicate tobacco products marketed with customary claims such as smoking pleasure as opposed to tobacco products

The district court framed the issue as "whether Congress has evidenced its clear intent to *withhold* from FDA jurisdiction to regulate tobacco products as customarily marketed." *Coyne Beahm*, 966 F. Supp. at 1380. However, we are of opinion that the issue is correctly framed as whether Congress intended to *delegate* such jurisdiction to the FDA. See *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208, 109 S. Ct. 468, 102 L.Ed.2d 493 (1988) (stating that "[i]t is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress"); *INS v. Chadha*, 462 U.S. 919, 953 n. 16, 955 n. 19, 103 S. Ct. 2764, 77 L.Ed.2d 317 (1983) (providing that agency action "is always subject to check by the terms of the legislation that authorized it; and if that authority is exceeded it is open to judicial review" and "Congress ultimately controls administrative agencies in the legislation that creates them"). This fundamental misconception by the district court of the principal issue in the case unavoidably skewed the remainder of its analysis.

Applying the principles set forth by the Supreme Court in *Chevron*, we examine whether Congress intended to give the FDA jurisdiction over tobacco products. Under *Chevron*, we first consider the intent of Congress because "[i]f the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron*, 467 U.S. at 842-43, 104 S. Ct. 2778. It is only if the intent of Congress is

marketed with specific therapeutic claims such as weight loss. Unless indicated otherwise, all references in this opinion are to tobacco products as customarily marketed.

ambiguous that we defer to a permissible interpretation by the agency. *Chevron*, 467 U.S. at 843, 104 S. Ct. 2778. And we note, with emphasis, that the Supreme Court has stated that “[a] precondition to deference under *Chevron* is a congressional delegation of administrative authority.” *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649, 110 S. Ct. 1384, 108 L.Ed.2d 585 (1990). Accordingly, no deference is due the FDA’s construction of the Act unless it is acting within the bounds of its congressionally-established authority. If the court can ascertain Congress’ intent on a particular question by applying the traditional rules of statutory construction, then it must give effect to that intent. *Chevron*, 467 U.S. at 843 n. 9, 104 S. Ct. 2778; see also *Cabell Huntington Hosp., Inc. v. Shalala*, 101 F.3d 984, 986 (4th Cir.1996) (stating that “[t]he goal of statutory interpretation is to implement congressional intent”). We also note that ascertaining congressional intent is of particular importance where, as here, an agency is attempting to expand the scope of its jurisdiction. See, e.g., *Adams Fruit Co.*, 494 U.S. at 650, 110 S. Ct. 1384 (quoting *Federal Maritime Comm’n v. Seatrain Lines, Inc.*, 411 U.S. 726, 745, 93 S. Ct. 1773, 36 L.Ed.2d 620 (1973)) (warning that “an agency may not bootstrap itself into an area in which it has no jurisdiction”); *ACLU v. FCC*, 823 F.2d 1554, 1567 n. 32 (D.C. Cir. 1987) (stating that “[w]hen an agency’s assertion of power into new arenas is under attack, therefore, courts should perform a close and searching analysis of congressional intent, remaining skeptical of the proposition that Congress did not speak to such a fundamental issue”), *cert. denied*, 485 U.S. 959, 108 S. Ct. 1220, 99 L.Ed.2d 421 (1988); *Hi-Craft Clothing Co. v. NLRB*, 660 F.2d 910, 916 (3d Cir. 1981) (noting that “[t]he more intense scrutiny that is appropriate when

the agency interprets its own authority may be grounded in the unspoken premise that government agencies have a tendency to swell, not shrink, and are likely to have an expansive view of their mission”).

Although the task of statutory construction generally begins with the actual language of the provision in question, *Mead Corp. v. Tilley*, 490 U.S. 714, 722, 109 S. Ct. 2156, 104 L.Ed.2d 796 (1989), the inquiry does not end there.¹⁰ The Supreme Court has often emphasized the crucial role of context as a tool of statutory construction. For example, the Court has stated that when construing a statute, courts “must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy.” *United States Nat’l Bank of Oregon v. Independent Ins. Agents of America, Inc.*, 508 U.S. 439, 455, 113 S. Ct. 2173, 124 L.Ed.2d 402 (1993) (quoting *United States v. Boisdore’s Heirs*, 49 U.S. (8 How.) 113, 122, 12 L.Ed. 1009, (1850)); see also *Regions Hosp. v. Shalala*, — U.S. —, 118 S. Ct. 909, 139 L.Ed.2d 895 (1998); *Massachusetts v. Morash*, 490 U.S. 107, 115, 109 S. Ct. 1668, 104 L.Ed.2d 98 (1989). Thus, the traditional rules of statutory construction to be used in ascertaining congressional intent include: the overall statutory scheme, *Offshore Logistics, Inc. v. Tallentire*, 477 U.S.

¹⁰ In fact, if application of the plain language of a statute “would produce a result demonstrably at odds with the intent of Congress . . . the intent of Congress rather than the strict language controls.” *Maryland State Dep’t of Educ. v. U.S. Dep’t of Veterans Affairs*, 98 F.3d 165, 169 (4th Cir. 1996) (citing *United States v. Ron Pair Enter., Inc.*, 489 U.S. 235, 242, 109 S. Ct. 1026, 103 L.Ed.2d 290 (1989)), *cert. denied*, — U.S. —, 118 S. Ct. 43, 139 L.Ed.2d 10 (1997).

207, 220-221, 106 S. Ct. 2485, 91 L.Ed.2d 174 (1986) (directing courts to examine the language of the statute as a whole); legislative history, *Atherton v. FDIC*, 519 U.S. 213, 117 S. Ct. 666, 136 L.Ed.2d 656 (1997); "the history of evolving congressional regulation in the area," *Dunn v. CFTC*, 519 U.S. 465, 117 S. Ct. 913, 137 L.Ed.2d 93, (1997); and a consideration of other relevant statutes, *United States v. Stewart*, 311 U.S. 60, 64, 61 S. Ct. 102, 85 L.Ed. 40 (1940) (explaining that "all acts *in pari materia* are to be taken together as if they were one law") (italics in original). With these general principles in mind, we begin our inquiry into the issue of whether Congress intended to delegate jurisdiction over tobacco products to the FDA.

A. Intrinsic Evidence

The FDA correctly contends that the language of the statute must be the starting point of our analysis. We agree that the first step of statutory construction is determining the plain meaning of the statutory text. In fact, the Court instructs that the inquiry ends with the statutory language when the language is unambiguous and "the statutory scheme is coherent and consistent." *Robinson v. Shell Oil*, 519 U.S. 337, 117 S. Ct. 843, 136 L.Ed.2d 808 (1997) (quoting *Ron Pair Enter.*, 489 U.S. at 240, 109 S. Ct. 1026).

However, the flaw in the limited approach suggested by the FDA and taken by the district court is that they examine only the literal meaning of the statutory definitions of drug and device.¹¹ See FDA Red Br. at

¹¹ For example, in its jurisdictional analysis, the district court purported to examine the "Text of the Federal Food, Drug, and

34 (stating that "the jurisdictional inquiry is at an end with the conclusion that cigarettes and smokeless tobacco are 'intended to affect the structure of any function of the body' within the meaning of the Act's drug and device provisions"); see also *Coyne Beahm*, 966 F.Supp. at 1380.

A mechanical reading of only the definitions provisions may appear to support the government's position that tobacco products fit within the Act's definitions of drugs or devices. However, an initial problem with the government's theory is that the definitions of drug and device require not only that the article "affect the structure or any function of the body," but also that these effects be intended. 21 U.S.C. §§ 321(g)(1)(C), 321(h)(3). As noted by the district court, "no court has ever found that a product is 'intended for use' or 'intended to affect' within the meaning of the [Act] absent manufacturer claims as to that product's use." *Coyne Beahm*, 966 F. Supp. at 1390. Even the FDA does not contend that tobacco manufacturers make any such claims. *Coyne Beahm*, 966 F. Supp. at 1389 n. 14.

Even if we were to accept the FDA's position that no other inquiry is permissible if tobacco products fall within the literal definition of drug or device, the jurisdictional inquiry would not end there. Both the FDA and the district court failed to examine the literal definitions in view of the language and structure of the

Cosmetic Act." *Coyne Beahm*, 966 F.Supp. at 1380. However, the court mentioned only the definitions sections of the statute and ignored the text of all of the mandatory operative provisions of the Act.

Act as a whole. Such holistic approach to statutory construction is well-supported by the case law. See, e.g., *Robinson*, 519 U.S. 337, 117 S. Ct. 843, 136 L.Ed.2d 808 (stating that statutory language must be examined by "reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole"); *Gustafson v. Alloyd Co.*, 513 U.S. 561, 570, 115 S. Ct. 1061, 131 L.Ed.2d 1 (1995) (instructing that acts of Congress "should not be read as a series of unrelated and isolated provisions"); *United States Nat'l Bank*, 508 U.S. at 455, 113 S. Ct. 2173 (quoting *United Savings Ass'n of Texas v. Timbers of Inwood Forest Assoc., Ltd.*, 484 U.S. 365, 371, 108 S. Ct. 626, 98 L.Ed.2d 740 (1988)) (explaining that statutory interpretation is a "holistic endeavor" that must include, at a minimum, an examination of the statute's full text, its structure, and the subject matter). Accordingly, our task is to examine whether tobacco products fit into the overall regulatory scheme created by Congress.

According to FDA Deputy Commissioner Schultz, "[a] fundamental precept of drug and device regulation in this country is that these products must be proven safe and effective before they can be sold." Statement by FDA Deputy Commissioner William B. Schultz before the Senate Comm. on Labor and Human Resources, 104th Cong., p. 8 (Feb. 22, 1996). In fact, the FDA's congressionally-established mission statement provides that the FDA is charged with protecting the public health by ensuring that human drugs are "safe and effective" and that "there is a reasonable assurance of the safety and effectiveness of devices intended for human use." 21 U.S.C. § 393(b)(2)(B), (C). During its rulemaking, the FDA found that tobacco products are "dangerous," "unsafe," and the cause of "great pain and

suffering from illness such as cancer, respiratory illnesses, and heart disease." 61 Fed. Reg. at 44,412. In addition, the FDA determined that over 400,000 people die each year from tobacco use. 61 Fed. Reg. at 44,412. Yet, the FDA has proposed to regulate tobacco products under a statutory provision that requires conditions on sale and distribution which provide a reasonable assurance of safety. 21 U.S.C. § 360j(e). According to the FDA, a determination of safety under the Act requires consideration of the risks of a product compared to the "countervailing effects of use of that product, including the consequences of not permitting the product to be marketed." 61 Fed. Reg. at 44,412-13. Thus, the FDA concluded that withdrawal of tobacco from the market poses significant health risks to addicted adults which outweigh the risks of leaving tobacco products on the market. 61 Fed. Reg. at 44,405, 44,412-44,413.

But that test is contrary to the statute. The statutory provision, 21 U.S.C. § 360c(a)(2)(C), provides that safety and effectiveness are to be determined by "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." See also *United States v. Rutherford*, 442 U.S. 544, 556, 99 S. Ct. 2470, 61 L.Ed.2d 68 (1979) (stating that "a drug is unsafe if its potential for inflicting death and physical injury is not offset by the possibility of therapeutic benefit"). According to the language of § 360c(a)(2)(C), the FDA's obligation is to strike a balance between the risks and benefits of the use of a certain product, not to weigh the risks of leaving a product on the market against the risks of taking a product off the market. The FDA is unable to state any real health benefit derived from leaving

tobacco products on the market. This is not to say that there are not other public policy reasons, such as impact on the national economy and the potential for a black market, weighing against a ban on tobacco products. However, this type of decision involving countervailing national policy concerns is just the type of decision left for Congress. By statute, the FDA's authority is limited to the balancing of health benefits and risks. 21 U.S.C. § 360c(a)(2)(C). Thus, its attempted analogy between tobacco products and chemotherapy drugs is not well taken. 61 Fed.Reg. at 44,413. These cancer-fighting drugs may be considered high-risk, but they have not been deemed "unsafe" by the FDA. Under the Act, the key to allowing these drugs to remain on the market is that their use produces affirmative health benefits which outweigh their risks. 21 U.S.C. § 360c(a)(2)(C). According to the FDA's own findings, tobacco products do not meet this test, for there is no health benefit from the use of tobacco. The FDA's inquiry into whether the risks of removing tobacco products from the market are greater than the risks of leaving them on the market is irrelevant under § 360c(a)(2)(C).

In the proposed regulations, the FDA characterized tobacco products as combination products containing drug and device components, but purported to regulate tobacco products as restricted devices under § 360j(e) of the Act. Section 360j(e) permits the FDA to place restrictions on the sale, distribution or use of a product which are necessary for a "reasonable assurance of safety" of the product. 21 U.S.C. § 360j(e). However, based on the FDA's characterization of tobacco products as unsafe, it is impossible to create regulations which will provide a reasonable assurance of safety.

Thus, the FDA cannot comply with the terms of the very statutory provision it has chosen as its basis for regulation. In addition to the fundamental conflicts described above, at least six internal inconsistencies arise when tobacco products are forced into the drug or device regulatory schemes of the Act.

First, § 355(a) of the Act requires that all new drugs be approved by the FDA before marketing. 21 U.S.C. § 355(a). The Act requires the FDA to disapprove applications for new drugs¹² if the drug is deemed unsafe or if there is not substantial evidence of its effectiveness. 21 U.S.C. § 355(d). This mandatory approval process presents an insurmountable problem for the FDA with respect to tobacco products because of the FDA's finding that they are unsafe. 61 Fed.Reg. at 44,412. In fact, the FDA has conceded that under the mandatory approval provisions, tobacco products would constitute unapproved new drugs. 60 Fed.Reg. 41,348 (1995) (FDA Proposed Rulemaking). As such, the Act would require the prohibition of the distribution and marketing of tobacco products. 21 U.S.C. §§ 331(d), 355(a).

The FDA attempts to avoid the problem inherent in the new drug approval requirement by classifying

¹² In relevant part, the Act defines a "new drug" as:

Any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof

. . .

21 U.S.C. § 321(p) (1).

tobacco products as combination products and then choosing to regulate them as devices rather than as drugs. The Act directs the FDA to determine the primary mode of action of a combination product. 21 U.S.C. § 353(g)(1). If the FDA determines that the primary mode of action is that of a drug, then it must assign "primary jurisdiction" over the product to the persons charged with premarket review of drugs. 21 U.S.C. § 353(g)(1)(A), (B). The FDA concedes that the "primary mode of action" of tobacco products is that of a drug.¹³ FDA Red Br. at 26 (citing 61 Fed.Reg. at 45,209-18; 44,400-03). Yet, it chose to regulate tobacco products devices under § 360j(e) of the Act. This transparent action by the FDA, obvious sophistry, taken in order to avoid the new drug provisions of the Act, reinforces the conclusion that regulation of tobacco products under the Act was not intended by Congress. However, the FDA's classification of tobacco products as devices could not avoid similar problems caused by other provisions of the Act.

Section 331(a) of the Act prohibits the introduction into or delivery in interstate commerce of any drug or device that is misbranded. 21 U.S.C. § 331(a). Under § 352(j), a drug or device is deemed to be misbranded if it is dangerous to health when used in the manner suggested in the labeling. 21 U.S.C. § 352(j). The FDA has concluded that the use of tobacco products is

¹³ Interestingly, the FDA chose to regulate tobacco products as devices even though it has regulated the nicotine products within its jurisdiction—nicotine patches, nicotine gum, and nicotine nasal sprays—as drugs. Approved Drug Products with Therapeutic Equivalence Evaluations, 1762 Food Drug Cosm. L. Rep. (CCH) 3-220, 221 (FDA May 29, 1996).

dangerous to health. 61 Fed.Reg. at 44,412. Thus, it is impossible for the labeling of tobacco products to suggest a nondangerous use. Accordingly, §§ 331(a) and 352(j) operate to make the continued marketing of tobacco products illegal.

A drug or device is also considered misbranded, and thus prohibited under § 331(a), if it does not include "adequate directions for use." 21 U.S.C. § 352(f)(1). According to the FDA, the requirement of adequate directions for use means "directions under which the layman can use a device safely and for the purposes for which it is intended." 61 Fed.Reg. at 44,464. The FDA can exempt drugs and devices from § 352(f)(1)'s directions requirement, but only if the information is "not necessary for the protection of public health." 21 U.S.C. § 352(f). The FDA has previously interpreted § 352(f) to mean that an exemption from the direction requirements may be granted when other circumstances (such as a physician's prescription) can reasonably assure safe use of the drug or device. 21 C.F.R. §§ 201.100-201.129, 801.109-801.127 (1996).

The FDA now contends that an exemption for tobacco products is appropriate, 61 Fed.Reg. at 44,410, because everyone knows how to use tobacco products and thus directions are not needed. See 61 Fed.Reg. at 44,465 (stating that tobacco products are "one of the most readily available consumer products on the market today. Consequently, the way in which these products are used is common knowledge."). However, the FDA violated its own interpretation of the Act by exempting tobacco products under § 352(f) without any assurances of safety. Because of the FDA's finding that tobacco products are unsafe, 61 Fed.Reg. at 44,412, it is

impossible to provide directions for safe use as required by the statute. In addition, the exemption is inapplicable because no assurance of safety can be given for inherently unsafe products such as tobacco. Again, the FDA's need to apply the statutory exemption demonstrates that the Act does not and cannot apply to tobacco products.

Similarly, a drug or device is also considered misbranded, and thus prohibited by § 331(a), if it fails to bear "adequate warnings against use . . . by children where its use may be dangerous to health." 21 U.S.C. § 352(f)(2). Unlike § 352(f)(1), this section does not permit any exemptions from the warning requirement. In support of its proposed regulations, the FDA cited widespread use of tobacco products by minors and focused on controlling youth use as a means of decreasing tobacco-related illnesses and deaths. See 61 Fed. Reg. at 45,238-243 (characterizing youth use of tobacco products as a "pediatric disease"). The FDA concluded that the warnings mandated by other federal statutes satisfy the Act's requirement for adequate warnings to children even though none of the statutorily-prescribed warnings address the particular dangers of youth use repeatedly emphasized by the FDA. See 15 U.S.C. § 1333, 4402 (requiring Surgeon General warnings about health risks posed by tobacco products); see also 61 Fed. Reg. at 44,465. The FDA was constrained to find that the warnings mandated by other federal statutes are sufficient because the applicable federal statutes do not permit federal agencies to add to or modify the congressionally-mandated warnings. 15 U.S.C. §§ 1334(a), 4406(a). Again, the contortions that the FDA has gone through demonstrate

that Congress did not intend its jurisdictional grant to the FDA to extend to tobacco products.

Furthermore, under 21 U.S.C. § 360c(b)(1), all devices intended for human use must be classified into one of three categories, Class I, II, or III, based on ascending degrees of dangerousness. Placement is appropriate in the class that will provide a "reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. § 360c(a)(1)(A)-(C). As discussed above, safety and effectiveness are determined by "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C). Three years after it first introduced the proposed regulations, the FDA has yet to place tobacco products into one of the three categories. However, the agency's own findings with respect to dangers to health require classification of tobacco products as a Class III device subject to premarket approval because they "[present] a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii)(II); see also 61 Fed. Reg. at 44,398, 44,412 (discussing dangers of tobacco use). Under the premarket approval process, tobacco products could not be approved without a showing that there is a reasonable assurance of safety and effectiveness of the products when used in the manner suggested by the labeling. 21 U.S.C. § 360c(a)(1)(C). The FDA contends that it will classify tobacco products at some point in the future and that the long delay is consistent with both the statutory framework and the agency's prior actions for other devices. 61 Fed. Reg. at 44,412; FDA Red Br. at 45. However, the real problem with attempting a classification is that all three categories of devices require reasonable assurances of safety and

effectiveness for the product. 21 U.S.C. § 360c(a)(1). As discussed earlier, the FDA cannot provide reasonable assurances of safety for a product that it has found to be inherently unsafe and dangerous. Thus, it has not, and more importantly, cannot comply with Congress' statutory classification directive because complying with the statute would trigger a ban on tobacco products, a result not intended by Congress.

Finally, the Act *requires* the FDA to issue an immediate cease-distribution order for all products found to cause "serious, adverse health consequences or death." 21 U.S.C. § 360h(e)(1).¹⁴ This order begins an agency process that may ultimately result in a recall order for the device. 21 U.S.C. § 360h(e)(2). The FDA has found that "tobacco use is the single leading cause of preventable death in the United States. More than 400,000 people die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease, often suffering long and painful deaths." 61 Fed.Reg. at 44,398 (citations omitted). According to the terms of the Act, these findings, standing alone, mandate that the FDA issue a cease-distribution order

¹⁴ In relevant part, § 360h(e)(1) provides:

If the [FDA] finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the [FDA] shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the device)

(A) to immediately cease distribution of such device;

...

21 U.S.C. § 360h(e)(1).

for tobacco products. Nevertheless, the FDA has no intention of complying with the requirements of the Act. See 61 Fed.Reg. at 44,419 (stating that the FDA will not ban tobacco products). The necessity of the FDA's avoidance of the statutory directives again demonstrates that Congress did not intend that the Act regulate tobacco products. A faithful application of the statutory language would lead to a ban on tobacco products—a result not intended by Congress.

The FDA makes a linguistic argument in an attempt to avoid the problem presented by this section. The statute provides that if the FDA finds there is a reasonable probability that a device will cause health problems or death, then the FDA "*shall* issue an order requiring . . . [the immediate] cease distribution of such device." 21 U.S.C. § 360h(e)(1)(A). However, the FDA contends that "shall" should be interpreted to mean "may." FDA Red Br. at 42-43. Even if we were to adopt this interpretation, the substance of our analysis would not change. As discussed above, the FDA has made the requisite finding of dangerousness under the statute. Thus, even if "shall" were interpreted as "may," the FDA still could exercise its discretion under the statute and ban tobacco products. And a failure to ban a product as dangerous as is tobacco, by the FDA's own findings, would necessarily be an abuse of discretion. But because an absolute ban falls outside the scope of congressional intent, construing the Act to cover tobacco products would be inconsistent with the will of Congress.

As demonstrated by the examples provided above, the FDA's need to maneuver around the obstacles created by the operative provisions of the Act reflects

congressional intent not to include tobacco products within the scope of the FDA's authority. The FDA argues that even if it has misapplied the Act, this error does not bear on the jurisdictional issue. However, the point is not merely that the FDA misapplied the Act, but these examples demonstrate the FDA's need to ignore and misapply the operative provisions of the Act before it can attain *its* end, not the end contemplated by Congress. Cf. *United States v. Two Plastic Drums*, 984 F.2d 814, 819 (7th Cir. 1993) (rejecting another recent attempt by the FDA to enlarge its jurisdiction and stating that "the only justification for this Alice-in-Wonderland approach is to allow the FDA to make an end-run around the statutory scheme"). The fact is that Congress did not equip the FDA with tools appropriate for the regulation of tobacco because it had no intention that the Act apply to tobacco products.

We do not dispute in this case that Congress has charged the FDA with protecting the public health and that tobacco products present serious health risks for the public. However, the Supreme Court has warned that "[i]n our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." *62 Cases of Jam v. United States*, 340 U.S. 593, 600, 71 S. Ct. 515, 95 L.Ed. 566 (1951). Based on our examination of the regulatory scheme created by Congress, we are of opinion that the FDA is attempting to stretch the Act beyond the scope intended by Congress.

B. *Extrinsic Evidence*

Pursuant to *Chevron's* instruction to employ the traditional tools of statutory construction, we now examine the events surrounding the 1938 passage of the Act as well as subsequent statements and actions by Congress and the FDA. These individual events are like pieces of a puzzle in that no single event is outcome determinative. However, when viewed as a whole, it is clear that Congress did not intend to give the FDA jurisdiction over tobacco products in 1938 when it passed the Act. See *MCI Telecomm. Corp. v. AT & T*, 512 U.S. 218, 228, 114 S. Ct. 2223, 129 L.Ed.2d 182 (1994) (stating that relevant time for determining congressional intent on meaning of statute is when controlling statute enacted). As discussed above, the fact that the operative provisions of the Act simply cannot accommodate tobacco products is a clear indication of congressional intent. Cf. *Gustafson*, 513 U.S. at 569, 115 S. Ct. 1061 (explaining that an operative provision of the Securities Act of 1933 does not define prospectus, the term at issue, but "does instruct us what a prospectus cannot be if the Act is to be interpreted as a symmetrical and coherent regulatory scheme"). Subsequent events outside the language of the statute only confirm our understanding of Congress' intent.

1. *Historical Actions of the FDA*

From 1914 until the present rulemaking attempt, the FDA had consistently stated that tobacco products were outside the scope of its jurisdiction. And, as early as 1898, the Supreme Court of Tennessee acknowledged the dangerous nature of tobacco products, characteriz-

ing cigarettes as "wholly noxious and deleterious to health," "inherently bad, and bad only," and "widely condemned as pernicious altogether." *Austin v. State*, 101 Tenn. 563, 48 S.W. 305, 306 (1898). Yet, the statute preceding the Act, the Pure Food and Drugs Act of 1906, Pub.L. No. 59-384, 34 Stat. 768 (1906), did not mention tobacco. As early as 1914, the FDA's predecessor agency stated that it had authority to regulate tobacco products if their labeling indicated use for "the cure, mitigation, or prevention of a disease," but not if labeled or used for "smoking or chewing or as snuff and not for medicinal purposes." Bureau of Chemistry, U.S. Dept. of Agriculture, 13 *Service and Regulatory Announcements* 24 (Apr. 2, 1914). Enacted in 1938, the present Act expanded the definition of drug from the definition provided in the Pure Food and Drugs Act of 1906 and also granted the FDA new authority to regulate "devices." Food, Drug, and Cosmetic Act, Pub.L. No. 75-717, 52 Stat. 1040 (1938). However, neither the Act nor its legislative history mention tobacco products.¹⁵

In the 60 years following the passage of the Act, the FDA has repeatedly informed Congress that cigarettes marketed without therapeutic claims do not fit within the scope of the Act. Ever since its beginning in the 1930s, the FDA has taken the position and made

¹⁵ Two of the main supporters of the Act were representatives from the two leading tobacco States—Senator Bailey (D-NC) and Representative Chapman (D-KY). See 83 Cong. Rec. 9094 (1938). In fact, Sen. Bailey and Rep. Chapman were among Senate and House managers of the Act in the Conference Committee. Had there been any indication that the Act might apply to tobacco products, we can only assume that such members of Congress would have expressed opposition to the Act.

statements indicating that the Act did not apply to cigarettes marketed without specific health claims. FDA/Dep't of Justice Brief in *ASH v. Harris*, 655 F.2d 236 (D.C. Cir. 1980), at 16. Again, in 1963, an FDA Bureau of Enforcement Guideline stated that "[t]he statutory basis for the exclusion of tobacco products from FDA's jurisdiction is the fact that tobacco marketed for chewing or smoking without accompanying therapeutic claims, does not meet the definitions in the Food, Drug, and Cosmetic Act for food, drug, device or cosmetic." Letter to Directors of Bureaus and Divisions and Directors of Districts from FDA Bureau of Enforcement (May 24, 1963), reprinted in *Public Health Cigarette Amendments of 1971: Hearings Before the Consumer Subcomm. of the Senate Comm. on Commerce on S. 1454*, 92d Cong. 240 (1972). When Congress later examined the issue of the FDA's jurisdiction during its consideration of tobacco-specific legislation, FDA Commissioner Charles Edwards testified regarding the FDA's lack of authority over cigarettes and stated that "if cigarettes were to be classified as drugs, they would have to be removed from the market because it would be impossible to prove they were safe for their intended [use]."¹⁶ Hearings on S. 1454 at 239. The Commissioner took the position that the Federal Cigarette Labeling and Advertising Act, discussed in greater detail below, reinforced that "the

¹⁶ The Commissioner cited several cases in support of the FDA's conclusion that it lacked authority over cigarettes as customarily marketed. See, e.g., *FTC v. Liggett & Myers Tobacco Co.*, 203 F.2d 955 (2d Cir. 1953), *affirming on opinion below*, 108 F. Supp. 573 (S.D.N.Y. 1952); *United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F.Supp. 847 (D.N.J. 1959); *United States v. 46 Cartons . . . Fairfax Cigarettes*, 113 F. Supp. 336 (D.N.J. 1953).

regulation of cigarettes is to be the domain of Congress." Hearings on S. 1454 at 242. The Commissioner then concluded that "labeling or banning cigarettes is a step that can be take[n] only by Congress. Any such move by the FDA would be inconsistent with the clear congressional intent." Hearings on S. 1454 at 242.

In 1977, Action on Smoking and Health (ASH), a public health group, petitioned the FDA to regulate cigarettes. ASH claimed that cigarettes were drugs because they contain nicotine which produces addiction in many smokers, and particularly in youth. Citizen Petition, FDA Docket No. 77P-0185, at 4-11 (May 26, 1977)[G. Br. Att. 77]. In rejecting ASH's petition,¹⁷ the FDA cited a 1953 Second Circuit opinion, *FTC v. Liggett & Myers Tobacco Co.*, 203 F.2d 955 (2d Cir. 1953), *affirming on opinion below*, 108 F. Supp. 573 (S.D.N.Y. 1952), for the proposition that cigarettes marketed without health claims by the vendor are not within the FDA's jurisdiction. Specifically, the FDA quoted with approval the following language from the court's opinion:

The legislative history, such as it is, coupled with indications of contemporaneous administrative interpretation leads me to the conclusion that Con-

¹⁷ A federal appeals court upheld the FDA's denial of jurisdiction. See *ASH v. Harris*, 655 F.2d 236 (D.C. Cir. 1980). In upholding the FDA's denial of jurisdiction, the court emphasized the relevance of the remarks of the district court in *Liggett*. In construing the identical language of the definitions in the Federal Trade Commission Act, the *Liggett* court stated: "[s]urely, the legislators did not mean to be as all-inclusive as a literal interpretation of [the definitions] would compel us to be." *ASH*, 655 F.2d at 240 (quoting *Liggett & Myers*, 108 F. Supp. at 576).

gress, had the matter been considered, would not have intended cigarettes to be included as an article "intended to affect the functions of the body of man" or in any other definition of "drug."

See Letter from FDA Commissioner Donald Kennedy to John F. Banzhaf, III, at 3 (Dec. 5, 1977) (quoting *Liggett & Myers*, 108 F. Supp. at 577) (stating that the FDA's consistent position has been that cigarettes marketed without health claims by vendors are not drugs within the Act).

In 1978, ASH filed a second petition, claiming that cigarettes were devices under the Act and thus were within the scope of the FDA's jurisdiction. *Citizen Petition*, FDA Docket No. 78P-0338 (Oct. 2, 1978). After reviewing the legislative history of the Act, the FDA stated that "[i]nsofar as rulemaking would relate to cigarettes or attached filters as customarily marketed, we have concluded that FDA has no jurisdiction under [the definition of device]. Therefore, no rulemaking is permissible as a matter of law." Letter from FDA Commissioner Jere E. Goyan to John F. Banzhaf, III and Peter N. Georgiades, at 12 (Nov. 25, 1980). In considering the effect of the Medical Device Amendments of 1976 which modified the definition of device to its current formulation, the FDA Commissioner stated:

Specifically, there is no evidence in the legislative history that Congress intended to include cigarettes within the definition of "device" nor does the legislative history contain any discussion of a possibility that cigarettes were "devices" within the prior definition.

The amendments were thoroughly considered, and the legislative history discusses the types of products intended to be regulated and the types of health hazards with respect to which the amendments were intended to provide authority. Cigarettes are not mentioned even though Congress was aware of the considerable public discussion of the health hazards of cigarette smoking. It is, therefore, not reasonable to consider cigarettes as "devices" when there was no discussion in the legislative history of congressional intent to provide jurisdiction over cigarettes or to provide authority suitable to the regulation of cigarettes.

Goyan/Banzhaf Letter, at 3. The FDA's holdings and statements that the Act fails to provide "authority suitable to the regulation of cigarettes" are consistent with part II.A's conclusion, *supra*, that the Act's regulatory scheme simply cannot accommodate tobacco products.

Again in 1989, the FDA Commissioner stated that: "it doesn't look like it is possible to regulate [tobacco products] under the Food, Drug and Cosmetic Act even though smoking, I think, has been widely recognized as being harmful to human health." Hearings Before the Subcomm. on Rural Development, Agriculture, and Related Agencies of the House Comm. on Appropriations, 100th Cong., 2d Sess. 409 (1989). The above statements evidence the FDA's position from 1914 until the present rulemaking attempt that, as a matter of law, it did not have jurisdiction to regulate tobacco products as customarily marketed. The FDA's public,

consistent, and longstanding interpretation¹⁸ of the Act gains even more significance when viewed in conjunction with the actions of Congress during the same time period.

2. Congressional Inaction

We recognize the general reluctance of courts to rely on congressional inaction as a basis for statutory interpretation. See *Brecht v. Abrahamson*, 507 U.S. 619, 632, 113 S. Ct. 1710, 123 L.Ed.2d 353 (1993) (noting that "[a]s a general matter, 'we are reluctant to draw inferences from Congress's failure to act'" (quoting *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 306, 108 S. Ct. 1145, 99 L.Ed.2d 316 (1988))). However, under certain circumstances, inaction by Congress may be interpreted as legislative ratification of or acquiescence to an agency's position. See *Bob Jones Univ. v. United States*, 461 U.S. 574, 601, 103 S. Ct. 2017, 76 L.Ed.2d 157 (1983) (stating that "[i]n view of its prolonged and acute awareness of so important an issue, Congress' failure to act on the bills proposed on this subject provides added support for concluding that Congress acquiesced in the IRS rulings"). In *Bob Jones*, the Court examined Congress' failure to modify

¹⁸ We do not mean to suggest that an agency is always irrevocably bound by its prior interpretations of a statute. However, we note that an agency's interpretation of a statutory provision that conflicts with the agency's earlier interpretation is "entitled to considerably less deference" than a consistently held agency view." *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 417, 113 S. Ct. 2151, 124 L.Ed.2d 368 (1993) (quoting *Watt v. Alaska*, 451 U.S. 259, 273, 101 S. Ct. 1673, 68 L.Ed.2d 80 (1981)). In addition, the evidence of legislative ratification also weighs against the FDA's actions in the present case.

two IRS rulings when the public and Congress were well aware of the position of the IRS. *Bob Jones*, 461 U.S. at 599-602, 103 S. Ct. 2017. In finding legislative acquiescence to the IRS position, the Court emphasized: extensive hearings held by Congress on the issue; the introduction and failure of numerous bills in Congress introduced to overturn the IRS's interpretation of the Internal Revenue Code; and Congress' awareness of the IRS position when enacting other, related legislation. *Bob Jones*, 461 U.S. at 599-601, 103 S. Ct. 2017; see also *United States v. Riverside Bayview Homes, Inc.*, 474 U.S. 121, 137, 106 S. Ct. 455, 88 L.Ed.2d 419 (1985) (finding legislative acquiescence and explaining that "a refusal by Congress to overrule an agency's construction of legislation" is particularly relevant "where the administrative construction has been brought to Congress' attention through legislation specifically designed to supplant it").

We are of opinion that the matter before us presents an equally strong case of legislative acquiescence.¹⁹ As noted by the district court, Congress has introduced numerous bills that would have granted the FDA jurisdiction over tobacco products. See *Coyne Beahm*, 966 F. Supp. at 1382 (stating that "members of Congress agreed with FDA's assertions that it lacked jurisdiction" and thus introduced bills expressly granting the FDA jurisdiction "in an effort to remedy the situation"). In fact, the district court listed 15

¹⁹ The district court attempted to distinguish the *Bob Jones* and *Riverside Bayview* cases by noting that they involved agency action rather than statements by an agency that it did not have jurisdiction to act. *Coyne Beahm*, 966 F. Supp. at 1383. We fail to see any real distinction and thus find the cases applicable.

different bills introduced in Congress which would have expressly granted the FDA jurisdiction over tobacco products. *Coyne Beahm*, 966 F. Supp. at 1382. However, none of these bills were enacted. As discussed above, FDA officials have testified at many congressional hearings regarding the FDA's lack of jurisdiction over tobacco products. See also *Coyne Beahm*, 966 F. Supp. at 1381. Thus, Congress has been well aware of the FDA's position that it lacked jurisdiction over tobacco products since 1914. On several occasions, Congress has enacted legislation to deal specifically with the dangers of tobacco products, but has never enacted legislation to overturn the FDA's interpretation of its jurisdiction under the Act. Accordingly, this is not a case where congressional inaction demonstrates "unawareness, preoccupation, or paralysis." See *Zuber v. Allen*, 396 U.S. 168, 185-86 n. 21, 90 S. Ct. 314, 24 L.Ed.2d 345 (1969). We believe that the actions rejected and taken by Congress with respect to the regulation of tobacco provide strong evidence of congressional intent that it, and not the FDA, controls the regulation of tobacco products.

3. Congress' Tobacco-Specific Legislation

Under *Chevron*'s instruction to apply the traditional rules of statutory construction, it is also appropriate to consider the provisions of the "whole law, and . . . its object and policy" in ascertaining the will of Congress. *Dole v. United Steelworkers of America*, 494 U.S. 26, 35, 110 S. Ct. 929, 108 L.Ed.2d 23 (1990) (quoting *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 51, 107 S. Ct. 1549, 95 L.Ed.2d 39 (1987)). Having examined the Act and prior actions of the FDA and Congress, we now take a closer look at three statutes and related amend-

ments (collectively referred to as the tobacco-specific legislation) enacted by Congress for the purpose of addressing public health concerns about the use of tobacco products.

The issue is not, in the words of the stalking horse set up by the government, whether these three statutes partially repeal or amend the Act to withhold jurisdiction over tobacco products from the FDA. FDA Red Br. at 57. Rather, we examine the tobacco-specific legislation as a part of our inquiry into congressional intent. As discussed above, we are of opinion that the statutory text, viewed as a coherent whole, clearly indicates that Congress did not intend the FDA's original jurisdictional grant to include tobacco products. Thus, the subsequent enactment of tobacco-specific legislation provides corroborating evidence of established congressional intent.

In January 1964, the publication of the first Surgeon General's report on smoking and health called the federal government's attention to the dangers of tobacco products. Dept. of Health, Education and Welfare, *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service* (1964); see also H.R. Rep. No. 289, 91st Cong., 1st Sess., at 5 (characterizing the 1964 Surgeon General's Report as the "principal basis" for regulatory efforts). Shortly thereafter, the House Committee on Interstate and Foreign Commerce initiated a series of hearings regarding the federal government's role in dealing with smoking-related health problems. Committee Chairman, Representative Oren Harris, stated that:

The purpose of these hearings will be, if we can reach that point, to determine the extent of authority under existing law to deal with the various aspects of this general field, and to determine whether any action of the Congress is warranted in the interest of public health. In other words, we want to find out under our responsibility whether or not legislative action is necessary, and if so, what kind.

Hearings Before the Comm. on Interstate and Foreign Commerce on Bills Regulating the Labeling and Advertising of Cigarettes and Relating to Health Problems Associated with Smoking, 88th Cong., 2d Sess. 23 (1964).

During the course of these hearings, Congress considered and rejected the option of granting the FDA jurisdiction over tobacco products. Of the eleven bills submitted to the Committee, two would have expressly amended the Act to make it applicable to tobacco products. 1964 Hearings at 2-12. These two bills proposed expansion of the Act to cover tobacco products by creating a new category of products subject to FDA jurisdiction. See 1964 Hearings at 4-7 (suggesting creation of new category entitled "smoking products"). These two bills also proposed new operative provisions applicable only to "smoking products."²⁰ 1964 Hearings at 4-7. As part of the hearings, Surgeon General Terry was asked whether the Department of Health, Education, and Welfare (HEW), the FDA's parent depart-

²⁰ The fact that the two proposed bills created a new jurisdictional category and new operative provisions for tobacco products is consistent with our analysis in part II.A, *supra*, which concludes that the current structure of the Act cannot accommodate tobacco products.

ment, had authority to regulate tobacco products. Dr. Terry's unqualified response was that his department did not believe that it had "such authority in existing laws governing the Public Health Service and Food and Drug Administration." 1964 Hearings at 56. Similar testimony was later provided by the Deputy Commissioner of the FDA. See Cigarette Labeling and Advertising: Hearings Before the House Comm. on Interstate and Foreign Commerce, 89th Cong., 2d Sess. 193 (1965) (statement of Deputy Commissioner Rankin that "[t]he Food and Drug Administration has no jurisdiction under the Food, Drug, and Cosmetic Act over tobacco, unless it bears drug claims"); see also 111 Cong. Rec. 13431 (1965). In addition, the Secretary of HEW, Anthony J. Celebrezze, warned the Committee that giving the FDA jurisdiction over tobacco products "might well" lead to a ban and that such a ban would be contrary to the intent of Congress and the will of the American public. See 1964 Hearings at 18 (stating that a ban would be "contrary to what, we understand, is intended or what, in the light of our experience with the 18th amendment, would be acceptable to the American people").

Following the hearings and consideration of the various bills, Congress responded to the Surgeon General's report by enacting The Federal Cigarette Labeling and Advertising Act (Cigarette Labeling Act), Pub.L. No. 89-92, 79 Stat. 282 (1965) (codified at 15 U.S.C. §§ 1331 *et seq.*). In general, the Cigarette Labeling Act required manufacturers to place specific health-hazard warnings from the Surgeon General on cigarette packaging, advertising, and billboards. 15 U.S.C. § 1333. The Cigarette Labeling Act also set forth con-

gressional policy regarding regulation of tobacco products:

It is the policy of the Congress, and the purpose of this chapter, to establish a *comprehensive Federal program* to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby

(1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and

(2) *commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.*

15 U.S.C. § 1331. Thus, the express goal of the Cigarette Labeling Act is to warn consumers about the health hazards of smoking while also protecting the national economy.

The district court apparently considered that the plaintiffs claimed that the separate preemption provision of the Cigarette Labeling Act precluded any further regulation of tobacco products except by Congress. See *Coyne Beahm*, 966 F. Supp. at 1385-1386. We do not think that the claim was so broad then, certainly it is not so broad now. While it is true that 15 U.S.C. § 1334, requires that no statement relating to smoking or health other than the statement required by § 1333, shall be required on any cigarette package, that

is not a statement excluding other regulation of tobacco products. But the fact that Congress has, some 27 years after the establishment of the FDA in its present form, enacted the Cigarette Labeling Act, is strong evidence that Congress has reserved for itself the regulation of tobacco products rather than delegating that regulation to the FDA.

Congressional policy, as set out in the Cigarette Labeling Act, cannot be harmonized with the FDA's assertion of jurisdiction over tobacco products. First, by enacting the Cigarette Labeling Act rather than other proposed legislation, Congress clearly rejected the proposed regulatory role for the FDA. Next, the Act charges the FDA with protecting the public health, but does not authorize the FDA to consider protection of commerce and the national economy. Thus, by the terms of its enabling statute, the FDA is not capable of complying with Congress' stated policy regarding the regulation of tobacco products. In addition, the congressionally-established regulatory plan of the Cigarette Labeling Act directly contradicts the FDA's mandatory requirements set forth in the Act. As discussed *supra* in part II.A, the Act prohibits the sale or distribution of unsafe devices. See, e.g., 21 U.S.C. §§ 331(a), 352(j). In contrast, the Cigarette Labeling Act recognizes the unsafe and dangerous nature of cigarettes, but permits continued marketing with consumer warnings. 15 U.S.C. §§ 1331, 1333. The decision by Congress to allow continued marketing of unsafe products cannot be reconciled with the operative provisions of the Act, primarily because the Act does not allow FDA consideration of the factors involved in Congress' policy determination. See 15 U.S.C. § 1331(2)

(establishing policy of protecting "commerce and the national economy").

Finally, in developing the Cigarette Labeling Act, Congress clearly considered and rejected a role for the FDA. The government does not produce any legislative history to the contrary. The legislative history of the Cigarette Labeling Act is thus important to understanding congressional intent because it reflects the historical context in which the Cigarette Labeling Act was developed. See *Radowich v. United States Att'y*, 658 F. 2d 957, 961 (4th Cir. 1981) (stating that courts should look at the "clearly expressed intention as expressed without dissent in the legislative history" to be certain that their construction of a statute is consistent with the "manifest purpose as clearly mirrored in the legislative history"). Thus, the Cigarette Labeling Act and the context in which it was enacted provides evidence of Congress' intent that the FDA not have jurisdiction over tobacco products. Subsequent legislation by Congress reinforces our understanding of this expressed congressional intent.

The Cigarette Labeling Act's advertising and labeling regulations originally were set to expire on June 30, 1969. In response, the Federal Communications Commission (FCC) introduced a proposal to ban all television and radio cigarette advertising. 34 Fed.Reg. 1959 (1969). In addition, the Federal Trade Commission (FTC) renewed its proposed rule from 1964. See 34 Fed. Reg. 7917 (1969) (citing health hazards of smoking and proposing warning statements for cigarette packages and advertisements).²¹ Again, Congress debated

²¹ We note that the FDA took no action at this time.

the role of administrative agencies in the regulation of tobacco products. See generally *Cigarette Labeling and Advertising: Hearings Before the House Comm. on Interstate and Foreign Commerce, 91st Cong., 1st Sess. (1969)*. The House Report stated:

The regulations [proposed by the FCC and the FTC] raise basic constitutional questions and would affect the growing, sale, and manufacturing of tobacco for cigarettes and the persons involved in or affected by those activities. These activities cut across the whole spectrum of commercial and social life in the United States. It is therefore an area where the Congress, if anyone, must make policy.

...

Aside from the questions of constitutional and statutory law which the two agencies' proposed rules raise, they are an assumption by these agencies of policymaking with respect to a subject matter on which the Congress has made policy . . . , [and] has stated its intention to be the exclusive policymaker on the subject matter. . . .

H.R.Rep. No. 289, at 4-5.

Following these debates and hearings, Congress amended the Cigarette Labeling Act by enacting the Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91- 222, 84 Stat. 87 (1970). Basically, the 1969 Act reenacted the Cigarette Labeling Act, but with several amendments.²² Notably, Congress did not amend or

²² For example, the 1970 amendments changed the wording of the warning to be included on cigarette packages, 15 U.S.C. § 1333;

replace 15 U.S.C. § 1331, the provision setting out its policy determination regarding the regulation of tobacco products.

Congress showed a continuing interest in the regulation of tobacco products with the Alcohol and Drug Abuse Amendments of 1983, Pub. L. No. 98-24, 97 Stat. 175, 178 (1983) (codified at 42 U.S.C. §§ 290aa *et seq.*). These amendments require the Secretary of HHS, FDA's parent agency, to submit certain reports to Congress every three years. 42 U.S.C. § 290aa-2(b). The statute directs the Secretary to report to Congress current findings on "the addictive property of tobacco" and to *recommend* "legislation and administrative action as the Secretary may deem appropriate." 42 U.S.C. § 290aa-2(b)(2)-(3). This statute evidences Congress' awareness of the addictive nature of tobacco products and its intent to retain control over further regulatory action.

In 1984, Congress again amended the Cigarette Labeling Act, but retained the basic regulatory approach established in 1965. See Comprehensive Smoking Education Act (Smoking Education Act), Pub. L. No. 98-474, 98 Stat. 2200 (1984) (amending the Cigarette Labeling Act). The Smoking Education Act required rotating warnings on cigarette packaging and advertising, 15 U.S.C. § 1333; established an Inter-agency Committee on Smoking and Health, including members from the FTC, the Department of Education, and the Department of Labor, but not from the FDA,

revised § 1334's express preemption provision; and made it unlawful to advertise cigarettes on electronic communications subject to FCC jurisdiction, 15 U.S.C. § 1335.

15 U.S.C. § 1341(b); and required annual disclosure of tobacco ingredients to the Secretary of HHS, 15 U.S.C. § 1335a. Quoting U.S. Surgeon General Dr. C. Everett Koop, the House Report recommending this legislation described cigarette smoking as "the most important public issue of our time." H.R.Rep. No. 805, 98th Cong., 2d Sess., at 12 (1984). Consistent with the prior actions of Congress discussed above, the House Report recognized that "[f]ederal laws that protect the public from hazardous food, drugs and consumer products do not apply to cigarettes." H.R. Rep. 805, at 12.

In 1986, Congress created a similar regulatory program for smokeless tobacco, but with some additions.²³ Comprehensive Smokeless Tobacco Health Education Act (Smokeless Tobacco Act), Pub.L. No. 99-252, 100 Stat. 30 (1986) (codified at 15 U.S.C. §§ 4401-4408). In general, the Smokeless Tobacco Act required specific health warnings in smokeless tobacco advertising and on packaging, 15 U.S.C. § 4402(a),(b); authorized the FTC to issue specified regulations regarding the content and form of label warnings, 15 U.S.C. § 4402(c); banned advertising on electronic communications subject to FCC jurisdiction, 15 U.S.C. § 4402(f); and required annual ingredient and nicotine-level reporting to the HHS Secretary, 15 U.S.C. § 4403. In addition, the Smokeless Tobacco Act authorized the Secretary of HHS to develop a program for informing the public of the health hazards caused by use of smokeless tobacco. 15 U.S.C. § 4401(a). Specifically, the Secretary is

²³ It is worth noting that Congress adopted a very similar approach to the one taken in the Cigarette Labeling Act, even though it had expressly recognized the addictive nature of tobacco. 42 U.S.C. § 290aa-2(b)(2).

instructed to make this information available to school systems for educational purposes. 15 U.S.C. § 4401(a)(1)(B). The statute also provided for technical and financial assistance to States for their development of educational programs about the dangers of smokeless tobacco and for establishing 18 as the minimum age for purchasing smokeless tobacco. 15 U.S.C. § 4401(b).²⁴ Finally, the Smokeless Tobacco Act requires the Secretary of HHS to submit biennial reports to Congress containing "a description of the effects of health education efforts," "an evaluation of the health effects of smokeless tobacco products," and "recommendations for legislation and administrative action." 15 U.S.C. § 4407(a).

Like the Cigarette Labeling Act, the Smokeless Tobacco Act also contains an express preemption provision. See 15 U.S.C. § 4406 (providing that "[n]o statement relating to the use of smokeless tobacco products and health, other than the statements required by section 4402 of this title, shall be required by any Federal agency to appear on any package or in any advertisement"). However, as discussed in relation to the Cigarette Labeling Act, this express preemption provision does not detract from our examination of the statute as a tool for determining congressional intent. In recommending passage of the Smokeless Tobacco Act, the House Report cited particular concerns about the popularity of smokeless tobacco with minors. See S. Rep. No. 209, 99th Cong., at 4 (1985), *reprinted in* 1986

²⁴ As discussed below, Congress built on the youth education and age limit provisions of the Smokeless Tobacco Act in the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992 (1992 Amendments), Pub.L. No. 102-321, 106 Stat. 394 (codified at 42 U.S.C. § 300x-26).

U.S.C.C.A.N. 7, 10 (stating that "a major reason for the development of a legislative proposal is the alarming incidence of use by children"). Thus, in 1986, Congress considered the very issues that the FDA now purports to address in its proposed regulations.

Within the context of the FDA's repeated stated positions that it had no jurisdiction, Congress enacted comprehensive legislation addressing many of the activities that the FDA now attempts to regulate, based on the same concerns relating to youth use now cited by the FDA. The enactment of the Smokeless Tobacco Act in no way supports a conclusion that Congress intended to give the FDA jurisdiction over tobacco products. To the contrary, the detailed scheme created by Congress evidences its intent to retain authority over regulation of smokeless tobacco. Cf. *Patterson v. McLean Credit Union*, 491 U.S. 164, 181, 109 S. Ct. 2363, 105 L.Ed.2d 132 (1989) (stating that courts "should be reluctant . . . to read an earlier statute broadly where the result is to circumvent the detailed remedial scheme constructed in a later statute"). The FDA may not, without empowerment by Congress, construct what it believes is a "better" regulatory scheme. *MCI*, 512 U.S. at 234, 114 S. Ct. 2223. If the FDA believed that additional regulation was needed, the Secretary should have recommended such action to Congress, as directed in the Smokeless Tobacco Act. 15 U.S.C. § 4407(a)(4).

In 1992, Congress again addressed the problem of youth access to tobacco products. The Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992 (1992 Amendments), Pub. L. No. 102-321, 106 Stat. 394, focused on regulation at the state level by providing financial incentives to States which

enact and enforce access restrictions for individuals under age 18. 42 U.S.C. § 300x-26.²⁵

The 1992 Amendments express clear congressional intent that States exercise their traditional police powers and take a primary role in attacking the problem of youth access to tobacco products. However, the FDA's proposed regulatory scheme would preempt much state regulation in this area, including more stringent regulations than those proposed by the FDA. The Act prohibits States from imposing on devices any requirements "different from, or in addition to" those imposed by the FDA. 21 U.S.C. § 360k(a). Thus, if the Act applied to tobacco products, § 360k(a) would prohibit States from addressing the problem of youth access. The FDA responds, FDA Red Br. p. 67, n. 16, that States "might" qualify for exemptions from preemption under § 360k(b). However, the possibility of a discretionary exemption does not take away the inherent conflict between the state regulatory role established by Congress and the FDA's proposed scheme. In developing its regulatory scheme for tobacco products, Congress made a policy determination that state participation was necessary for effective regulation of

²⁵ More specifically, States are eligible for the financial incentives only if they: (1) prohibit sales to individuals under age 18, 42 U.S.C. § 300x26(a)(1); (2) enforce the prohibition in a way that "can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18," 42 U.S.C. § 300x-26(b)(1); (3) conduct "random, unannounced inspections" of retailers to check compliance, 42 U.S.C. § 300x-26(b)(2)(A); and (4) make annual reports to the HHS Secretary regarding the manner and success of state enforcement activities, 42 U.S.C. § 300x-26(b)(2)(B).

youth access. Allowing the FDA to override this decision would be contrary to congressional intent.

Over the last 60 years, Congress has enacted numerous statutes and amendments for the regulation of tobacco products. Throughout this period, Congress was well aware of the dangers of tobacco products and of the FDA's consistent position that it had no jurisdiction over tobacco products. Yet, Congress took no steps to overturn the FDA's interpretation of the Act, that it had no jurisdiction over tobacco products as customarily used. In fact, Congress deliberately rejected a role for the FDA during its consideration of various legislation from 1965 through 1993.²⁶ Instead, Congress developed a regulatory scheme whereby it retained the position of policymaker for the industry.²⁷ In addition, it developed a scheme whereby designated agencies would periodically report any new information and recommendations for legislation or regulation to Congress.²⁸ Taken together, these actions by Congress are relevant and corroborative evidence that Congress never intended to give the FDA jurisdiction over tobacco products.

²⁶ Between 1965 and 1993, at least 13 bills were introduced in Congress which would have given the FDA jurisdiction over tobacco products. None of these bills were enacted.

²⁷ Although Congress has given the FTC limited authority to regulate advertising related to tobacco products, this power is limited by the tobacco-specific legislation. 15 U.S.C. §§ 1336m, 4404-06.

²⁸ The HHS, FTC, and Interagency Committee are all directed to make periodic reports to Congress including information on the health effects of tobacco products, the addictive nature of tobacco products, cigarette advertising. See e.g., 15 U.S.C. §§ 1337(a), (b), 1341(a)-(c); 42 U.S.C. § 290aa-2.

III. Conclusion

This is not a case about whether additional or different regulations are needed to address legitimate concerns about the serious health problems related to tobacco use, and particularly youth tobacco use, in this country. At its core, this case is about who has the power to make this type of major policy decision. As the Supreme Court has previously stated about a different agency and its enabling statute, neither federal agencies nor the courts can substitute their policy judgments for those of Congress. See *MCI*, 512 U.S. at 234, 114 S. Ct. 2223 (stating that "our estimations, and the [FCC's] estimations, of desirable policy cannot alter the meaning of the federal Communications Act of 1934"). In rejecting the agency's interpretation of its enabling statute, the *MCI* Court characterized the agency's action as "effectively the introduction of a whole new regime of regulation . . . which may well be a better regime but is not the one that Congress established." *MCI*, 512 U.S. at 234, 114 S. Ct. 2223. Accordingly, we do not, indeed cannot, pass judgment on the merits of the regulatory scheme proposed by the FDA. By its *ultra vires* action, the FDA has exceeded the authority granted to it by Congress, and its rulemaking action cannot stand.

We are thus of opinion that Congress did not intend to delegate jurisdiction over tobacco products to the FDA. Accordingly, the judgment of the district court is

REVERSED.²⁹

²⁹ This footnote is added to make clear that the judgment of the district court regarding the construction of 21 U.S.C. § 360j(e), *Coyne Beahm*, 966 F. Supp. at 1399-1400, is vacated. The district court's construction of § 360j(e) was based on its erroneous holding that the FDA had authority to promulgate regulations regarding tobacco products. Had the district court reached the correct conclusion on the jurisdictional issue, there would have been no occasion to address the construction of § 360j(e). Accordingly, we vacate the district court's decision on that issue which is the subject of the government's appeal. We express no opinion on that question, and our decision should not be construed as either agreeing with or disagreeing with the district court's decision on the construction of § 360j(e).

K.K. HALL, Circuit Judge, dissenting:

The FDCA delegates to the FDA the duty of promulgating and enforcing regulations aimed at protecting the nation's citizens from misbranded and unsafe drugs and food. After years of considering an array of evidence, much of it only recently brought to light, the FDA decided to regulate a product that is estimated to cause some 400,000 deaths a year. While not actually disputing that tobacco products deliver a drug, nicotine, into the body, the majority would deny to the FDA the authority to act to address this acknowledged health threat. I dissent.

Tobacco products fit comfortably into the FDCA's definitions of "drug" and "device." Inasmuch as cigarettes and smokeless tobacco are responsible for illness and death on a vast scale, FDA regulations aimed at curbing tobacco use by children cannot possibly be contrary to the general intent of the FDCA to protect the public health. But even when we expand our search for legislative intent beyond the words of the statute, the evidence falls far short of demonstrating that Congress intended to deny or withdraw jurisdiction over tobacco from the FDA. Therefore, on the major question before us, I would affirm the district court's denial of summary judgment to the companies to the extent such judgment turns on the issue of the FDA's authority to regulate tobacco products.

As a consequence of this view, I must also reach those subordinate issues not discussed by the majority. I would affirm the denial of summary judgment to the companies on the issue of the FDA's choice of the "combination-products" regulatory scheme. I believe,

however, that the district court erred in ruling that the FDA cannot, as a matter of statutory law, restrict the advertising of tobacco pursuant to the agency's authority to regulate the "sale" of such products.

I

When reviewing an agency's construction of a statute, we must first ask "whether Congress has directly spoken to the precise question at issue." *Chevron, U.S.A., Inc., v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842, 104 S. Ct. 2778, 81 L.Ed.2d 694 (1984). The usual rule is to enforce the plain language of a statute according to its terms. *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 241, 109 S. Ct. 1026, 103 L.Ed.2d 290 (1989). Whether the language is plain is "determined by reference to the language itself, the specific context in which the language is used, and the broader context of the statute as a whole." *Robinson v. Shell Oil Company*, 519 U.S. 337, 117 S. Ct. 843, 846, 136 L.Ed.2d 808 (1997). Here, the language is plain, and the context does not command a result contrary to the plain meaning.

The majority devotes approximately three paragraphs to the words that form the heart of the FDA's jurisdictional claim: "[T]he term 'drug' means . . . articles (other than food) intended to affect the structure or function of the body." 21 U.S.C. § 321(g)(1)(C). While as much as conceding that tobacco products fit the FDCA's "literal" definition of drug, the majority concentrates instead on what it believes is abundant evidence *elsewhere* demonstrating that Congress has never intended that tobacco come under FDA authority. Despite the apparent agreement about the "literal"

meaning of "drug" and "device," a few words are necessary to set the stage before moving on to a discussion of the "context" of the FDCA.

A

The rulemaking record contains voluminous evidence of the pharmacological effects of nicotine; in addition to being highly addictive, nicotine acts as a stimulant, tranquilizer and appetite suppressant. *See* 61 Fed.Reg. 44665-66 (1996). Under these assumed facts, nicotine clearly "affect[s] the structure or function of the body of man . . .", and I do not understand the majority to be saying otherwise. The only arguable impediment to a complete fit between the terms of the statute and tobacco products is the word "intended."

B

Building on the conclusion that the nicotine in tobacco products is highly addictive, the FDA proffered four independent rationales to satisfy the additional requirement that tobacco products be "intended" to affect the body: (1) a reasonable manufacturer would foresee that consumers would use the product to satisfy addiction, *see* 61 Fed. Reg. 44634, 44701-39; (2) most consumers do in fact use tobacco products to satisfy addiction, *see id.* at 44233; (3) the manufacturers have long known that consumers use the products for the pharmacological effects, *see id.* at 44849; and (4) the manufacturers design the products to deliver active doses of nicotine, *see id.* at 44951. On reasoning with which I agree, the district court held that the FDA could proffer evidence in support of the first and second of these rationales. *Coyne Beahm*, 966 F. Supp. at 1388-

92. In addition, I would also permit the use of recently disclosed evidence, including heretofore-secret company documents, that establish that the companies have known about the addictive qualities of their products for years and that cigarettes are deliberately manipulated to create and sustain addiction to nicotine.

My dictionary contains the following definitions of "intend": "1. To have in mind: PLAN. 2a. To design for a particular purpose. b. To have in mind for a particular purpose." WEBSTER'S II NEW RIVERSIDE UNIVERSITY DICTIONARY (1984). As a matter of simple English, the resultant effect on the body—nicotine addiction—is *intended* when the manufacturer (as we are assuming for the purposes of this appeal) deliberately designs the product to have that effect. This meaning is the primary, literal, and most common one attached to the word "intend," and it is ordinarily the one we should use. See *Asgrow Seed Co. v. Winterboer*, 513 U.S. 179, 187, 115 S. Ct. 788, 130 L.Ed.2d 682 (1995) ("When terms used in a statute are undefined, we give them their ordinary meaning."). The majority's argument does not convince me that we should abandon this common sense rule in this situation.

Prior to these rules, the FDA had "asserted jurisdiction over cigarettes only when health claims were made by the vendors or manufacturers." *Action on Smoking and Health v. Harris*, 655 F.2d 236, 239 & n. 7 (D.C.Cir.1980) [hereinafter *ASH*] (citing as examples *United States v. 35½ Bulk Cartons Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (D.N.J.1959), in which cigarettes were marketed as weight reduction aids, and *United States v. 46 Cartons Fairfax Cigarettes*, 113 F.

Supp. 336 (D. N.J. 1953), in which cigarettes were marketed as helping to prevent respiratory diseases). No other court, however, has been confronted with the type and quantity of evidence collected during the rule-making process in this case; the strength of nicotine's addictive qualities, the extent of the health problems created by tobacco products, and the complicity of the manufacturers bring us to a different place than we have been before.

Products deliberately designed to create and sustain addiction are not likely to be marketed as such; indeed, such products are more likely listed elsewhere in Title 21 among the illegal controlled substances. It strikes me as patently absurd to contend that cigarettes and smokeless tobacco, products that are (under the assumed facts) actually designed to exert powerful and quintessentially drug-like effects on the users, should escape FDA regulation because the products are marketed as essential accoutrements of a more exciting or more sophisticated lifestyle.

II

Tobacco products, then, come squarely within the plain terms of the FDCA. If the words of a statute are plain, "absent any 'indication that doing so would frustrate Congress's clear intention or yield patent absurdity, our obligation is to apply the statute as Congress wrote it.'" *Hubbard v. United States*, 514 U.S. 695, 703, 115 S. Ct. 1754, 131 L.Ed.2d 779 (1995) (quoting *BFP v. Resolution Trust Corporation*, 511 U.S. 531, 570, 114 S. Ct. 1757, 128 L.Ed.2d 556 (1994) (Souter, J., dissenting)), quoted in *Dunn v. Commodity Futures Trading Commission*, 519 U.S. 465, 117 S. Ct.

913, 916, 137 L.Ed.2d 93 (1997). The questions, then, should be: Does upholding FDA jurisdiction over tobacco frustrate clear congressional intent to withhold such jurisdiction? Is it patently absurd? Does it "conflict with any other section of the Code, or with any important state or federal interest, [or] is a contrary view suggested by the legislative history[?]" *Ron Pair*, 489 U.S. at 243, 109 S. Ct. 1026. In other words, given the plain language used in § 321(g)(1)(C), the question should be whether the intent manifested by the words used—that tobacco products are "drugs [sic] delivery devices" subject to FDA regulation—is trumped by evidence to the contrary.

The majority seeks to show that the "context" of these readily understood words demonstrates that Congress really meant something else where tobacco is concerned. This search for context takes us into "the overall regulatory scheme created by Congress" (Maj. op. at 163) and "the history of evolving congressional regulation in the area" (Maj. op. at 162) (citation omitted), the legislative history of the FDCA and related statutes, and even congressional inaction. I will address each avenue explored by the majority.

A

The majority opens with this argument: The FDA's mandate is to prevent the marketing of any drug or device that is found to be unsafe; tobacco products are unsafe; to allow the continued sale of cigarettes is completely at odds with such mandate; *ergo*, the regulations must be struck down. But whether the regulations contravene the statute is a question wholly apart from whether *any* regulations could be issued. *How* the

FDA has chosen to regulate tobacco has no bearing on the question of *whether* that agency has the authority to regulate it at all, particularly when it is agreed that the power to regulate under the FDCA includes the power (under the assumed facts) to ban tobacco products completely. The FDA made an eminently reasonable decision to focus on preventing addiction among children while permitting sales to adults. *See* Fed. Reg. 44398-99, 44412-13. It is no argument to say that the FDA can do nothing because it could have done more.

B

The majority's analysis of the "extrinsic evidence" of congressional intent stands on three legs: The lack of any mention of tobacco in the statute itself or the legislative history of the 1938 Act; the FDA's consistent disavowal of any intention of taking jurisdiction over tobacco, and, concomitantly, the general assumption that the agency was right; and the series of tobacco-related statutes enacted over the last thirty years.¹

The FDCA

In construing remedial legislation, we must be ever mindful of the salutary purpose of the statute.

¹ As a corollary to this third point, the majority also relies on congressional *refusal* to enact legislation that would have expressly given the FDA the authority it now claims. *See* Maj. op. at 169-71. To whatever extent this inaction may be interpreted as "ratification" of the FDA's prior (no tobacco jurisdiction) position, it would appear that Congress's continued inaction in the face of all that has followed the FDA's announcement of the proposed rule three years ago (*see* 60 Fed. Reg. 41314) would more than offset any ratification effect to be gleaned from the earlier inaction.

The historical expansion of the definition of drug, and the creation of a parallel concept of devices, clearly show, we think, that Congress fully intended that the Act's coverage be as broad as its literal language indicates—and equally clearly, broader than any strict medical definition might otherwise allow. [W]e are all the more convinced that we must give effect to congressional intent in view of the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health. . . .

United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 798, 89 S. Ct. 1410, 22 L.Ed.2d 726 (1969).² The majority starts off on the wrong foot when it asks “whether Congress intended to delegate jurisdiction over tobacco products to the FDA.” Maj. op. at 162.

Congress did not “intend” that any particular product be included; as the district court noted, “[r]ather than itemize each product subject to regulation under the FDCA, Congress defined these categories broadly so that each encompasses a wide range of products.”

² Justice Frankfurter put it this way:

The purposes of this legislation [FDCA] touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.

United States v. Dotterweich, 320 U.S. 277, 280, 64 S. Ct. 134, 88 L. Ed. 48 (1943).

Coyne Beahm v. FDA, 966 F.Supp. at 1380. An exhaustive list of covered products was neither feasible nor necessary; effective regulation required flexibility within broad parameters.

Pointing out the obvious—that the FDCA was not originally directed at tobacco—gets us nowhere. No one contends that Congress foresaw in 1938 that tobacco was or might someday be included as a “drug” under the FDCA. The operative congressional intent at the outset was simply to confer broad discretionary powers on the FDA to regulate “drugs” and “devices.” The FDCA was written broadly enough to accommodate both new products and evolving knowledge about existing ones, and it was written that way on purpose.

FDA's Prior Position

Until the rulemaking began in 1995, the FDA had interpreted the FDCA to include tobacco products only when health claims were made. See Maj. op. at 168-69. The agency's refusal even extended to opposing citizens' petitions to regulate cigarettes on essentially the same basis that is used in the regulations today. See, e.g., *ASH*, 655 F.2d at 236. The agency's current position is a response to the increasing level of knowledge about the addictive nature of nicotine and the manufacturer's deliberate design to enhance and sustain the additive effect of tobacco products. When the early tobacco-specific statutes were being debated in Congress, the essential link between tobacco and illness had not yet been proven to the satisfaction of all. For instance, during the floor debate on amendments to the FCLAA, Rep. Perkins stated that

[i]t is my feeling that not one of the tobacco farmers in my district would knowingly produce any commodity which, when consumed, would cause the dread diseases which have been claimed to be associated with tobacco. But the claims . . . are not proved. Tobacco has been impeached in passion but it had not been convicted in fact. Facts, cold hard facts are the basis upon which congress should legislate.

Cigarette Labeling and Advertising: Hearings Before the House Comm. on Interstate and Foreign Commerce, 91st Cong. 16 (1969). Well, the "cold hard facts" are now in.

It is a familiar canon of administrative law that an agency can change its view of what action is possible or necessary, particularly when new facts come to light. See *Rust v. Sullivan*, 500 U.S. 173, 186-87, 111 S. Ct. 1759, 114 L.Ed.2d 233 (1991) ("An agency . . . must be given latitude to adapt its rules and policies to the demands of changing circumstances") (citations and internal quotation marks omitted). Even when upholding the FDA's earlier denial of its own power to regulate tobacco, the court added the following caveat:

Nothing in this opinion should suggest that the [FDA] is irrevocably bound by any long-standing interpretation and representations thereof to the legislative branch. An administrative agency is clearly free to revise its interpretations. . . . The very structure of the [FDCA] which the FDA must administer, moreover, calls for case-by-case analysis. Should an agency depart from its prior

interpretations, however, it must provide a reasoned explanation for its action. . . . [citations omitted].

ASH, 655 F.2d at 242 n. 10.

Under the facts found by the FDA during the rule-making process, it is now a scientific certainty that nicotine is extremely addictive and that a large majority of tobacco users use the product to satisfy that addiction; even more important to my mind is the new evidence that the manufacturers design their products to sustain such addiction. The administrative record in this case is a perfect illustration of why an agency's opportunity to adopt a new position should remain open.

The Tobacco Statutes

As products of the democratic process, each tobacco-specific statute is a balance of health, economic, and other concerns. The majority cites this body of legislation as "corroborating evidence of established congressional intent" to withhold jurisdiction over tobacco from the FDA. Maj. op. at 171. Again, I think the majority's approach ignores the fundamental source of intent, the words of the statute itself. Nevertheless, closer examination of these tobacco statutes reveals that they form something less than Congress's "comprehensive program" to address the tobacco problem. Absent a discernable intent to *exclude* future FDA action,³ that these statutes were written with knowl-

³ Congress certainly knows how to exempt tobacco. The only mention of tobacco in the FDCA was added in 1994 to explicitly

edge that the FDA forswore jurisdiction over tobacco does not supply that intent.

The first in this series, the Federal Cigarette Labeling and Advertising Act (FCLAA),⁴ was enacted in response to the Surgeon General's ground-breaking 1964 report linking smoking to health problems. The companies describe it as a statute that "set the boundaries of the federal regulatory role," "clearly expresses a congressional intent that precludes FDA jurisdiction over tobacco products," "embodied the view that Congress, itself, should retain all policy making authority as to tobacco, even in areas open to regulation," "ratified the established understanding that FDA does not have jurisdiction over tobacco products," "ruled out any later reading of the FDCA as an 'implicit' delegation to FDA . . . of authority to decide whether or how to regulate tobacco products and whether to ban them." Companies' Opening br. 13, 18-20. An examination of the statute reveals something considerably more modest, something that will not bear anything approaching the weight placed upon it by the companies or the majority.

The majority's focus is § 1331, which reads:

remove tobacco from the new exemption of "dietary supplements" from the definition of "drug." See Pub. L. No. 103-407, § 3(a), 108 Stat. 4325, 4327 (codified at 21 U.S.C. § 321(ff)). The criminal laws regarding narcotics incorporate the definition of "drug" found in the FDCA, see 21 U.S.C. § 802(12), but the definition of "controlled substance," which includes "a drug," specifically excludes tobacco. See 21 U.S.C. § 802(6).

⁴ The Comprehensive Smokeless Tobacco Health and Education Act, 15 U.S.C. §§ 4401-4407, more or less mirrors the FCLAA.

It is the policy of the Congress, and the purpose of this chapter, to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby—

- (1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and
- (2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.

This is a far cry from a comprehensive federal *tobacco* program; it is little more than a mild response to one of the earliest official recognitions of an emerging health issue.

The narrowness of the FCLAA was emphasized in *Banzhaf v. FCC*, 405 F.2d 1082 (D.C. Cir. 1968), where the court was confronted with a post-FCLAA ruling by the FCC that required radio and television stations that carried cigarette commercials to devote significant broadcast time to permit the case to be made against smoking. Then, as they do today, the tobacco companies argued that the FCLAA embodied a clear congressional intent to preclude intrusions into the regulation of tobacco by any agency. See *id.* at 1088. Judge Bazelon, however, saw things differently:

[T]here are positive indications that Congress's "comprehensive program" was directed at the relatively narrow specific issue of regulation of "cigarette labeling and advertising." . . . Nothing in the [FCLAA] indicates that Congress had any intent at all with respect to other types of regulation by other agencies—much less that it specifically meant to foreclose all such regulation. If it meant to do anything so dramatic, it might reasonably be expected to have said so directly. . . .

Id. at 1089 (footnotes omitted) (quotations in original).⁵ The next thirty years would see several more small steps that, even when considered together, fall far short of a comprehensive program, and even shorter of a demonstration that Congress intended to preclude the exercise of jurisdiction now being asserted by the FDA.

Following the FCLAA, the next step in what the companies characterize as Congress's ongoing program was the Public Health Cigarette Smoking Act of 1969, which amended the FCLAA in response to proposed incursions into the field by the FCC and FTC by way of proposed regulations that would have restricted tobacco advertising. Again, Congress addressed only advertising, this time in the electronic media, and short-circuited the roles proposed by the agencies for themselves.

⁵ In *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 514, 112 S. Ct. 2608, 120 L.Ed.2d 407 (1992), the Court described the purposes of the FCLAA as informing the public of the health risks and "protecting the national economy from the burden imposed by diverse, nonuniform, and confusing cigarette labeling advertising regulations" [footnote omitted].

Thirteen years later, Congress enacted the Alcohol and Drug Abuse Amendments of 1983, which simply directs the Secretary of HHS to report to Congress every three years on "the health consequences of drug abuse in the United States [and] current research findings made with respect to drug abuse, including current findings on . . . the addictive property of tobacco" and to include recommendations for "legislation and administrative action as the Secretary may deem appropriate." 42 U.S.C. § 290aa-2(b). This does not, as the majority asserts, "evidenc[e] Congress' . . . intent to retain control over further regulatory action." Maj. op. at 174. It is more an acknowledgment that because the HHS (and the FDA), as the experts in the complex field of drug abuse, had and would continue to have a crucial role to play, the Secretary was required to ask Congress for any *additional* tools it needed get to perform that role effectively.

The Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992 [ADAMHA], the last brick in the purported congressional tobacco program, provides financial incentives to the States to enforce their own restrictions on access to tobacco by minors. The majority argues that the FDA regulations would conflict with this congressional determination that the States should take an active role in addressing the youth access problem because the FDCA preempts any different restrictions on devices. See 21 U.S.C. § 360k(a). This overstates the case.

ADAMHA restructured block grant programs aimed at substance abuse and mental health services; only a few provisions relate to underage smoking. See 42

U.S.C. § 300x-26. ADAMHA does not demonstrate an intent on Congress's part that the states "take the primary role" in addressing the problem of underage smoking, and it certainly does not "establish" a regulatory role for the states. Maj. op. at 175-76. Although the FDA's proposed regulations would preempt some state laws, the exercise of FDA authority over tobacco would not "prohibit the States from addressing the problem of youth access." *Id.* The proposed rule can co-exist with most of the states' separate laws prohibiting sales to minors and imposing other restrictions on tobacco sales. Even the few more stringent state or local restrictions that are preempted by the FDA's proposed regulations (*see* 61 Fed. Reg. 44548-50) might qualify for an exemption from preemption, thereby further minimizing conflicts. *See* 21 U.S.C. § 360k(b). An overlap between two regulatory systems does not require wholesale jettisoning of one in favor of the other. *See Connecticut Nat'l Bank v. Germain*, 503 U.S. 249, 253, 112 S. Ct. 1146, 117 L.Ed.2d 391 (1992) ("Redundancies across statutes are not unusual events in drafting, and so long as there is no 'positive repugnancy' between two laws, a court must give effect to both") (internal citation omitted).

C

Tobacco is different from the articles commonly associated with the word "drugs," the FDA regulations are indeed the result of turnaround in agency thinking, and tobacco was most probably not on anyone's mind when the FDCA was enacted. But the FDCA was broadly worded by design. In an area in which complex new products (and old products, seen in the light of new evidence) pose the potential for grievous harm,

Congress deemed it necessary to delegate to an expert—the FDA—the job of monitoring drugs. Cigarettes and smokeless tobacco clearly fit within the literal terms of the FDCA. Absent a showing that following these statutory terms would be absurd or somehow frustrate congressional intent, we are bound to uphold FDA jurisdiction.

The FDA's denials that it had any authority over tobacco were certainly part of the background against which Congress passed tobacco-related legislation in the thirty years following the Surgeon General's 1964 report, but this series of statutes is hardly an argument for "legislative ratification" (Maj. op. at 170 n.18) of the FDA's prior position that the agency was powerless to act. It is agreed, moreover, that an agency is permitted to change its mind, particularly in response to new facts, so the real question is whether all that has gone before—the tobacco statutes, the consistent denials by the FDA—is sufficient to demonstrate a clear intent on Congress's part to *preclude* FDA jurisdiction. The evidence offered by the companies falls far short.

III

Having decided that the FDA has no jurisdiction over tobacco products, the majority had no reason to address whether cigarettes and smokeless tobacco were "devices" and whether the choice of regulatory regime—as a combination product, pursuant to the device authorities—was permissible. I agree with and adopt the district court's reasoning on these points entirely. *See Coyne Beahm*, 966 F. Supp. at 1393-97.

IV

Another issue not reached by the majority is whether the FDA may restrict the advertising of tobacco products.⁶ On this point, I disagree with the district court's conclusion that the advertising regulations exceeded the FDA's statutory authority.

The FDA found that "cigarette and smokeless tobacco use begins almost exclusively in childhood and adolescence." 61 Fed.Reg. 45239. Minors are particularly vulnerable to Madison Avenue's exhortations, plastered on racing cars and outfield fences, to be cool and smoke, be manly and chew, and the FDA found "compelling evidence that promotional campaigns can be extremely effective in attracting young people to tobacco products." *Id.* at 45247.⁷ The FDA chose to attack the problem by attempting to reduce the pressures to start using tobacco in the first place.

The pertinent portion of the of the 1976 Medical Device Amendments, 21 U.S.C. § 360j(e), provides:

The Secretary may by regulation require that a device be restricted to sale, distribution, or use . . .

⁶ In view of its ruling on statutory grounds, it was unnecessary for the district court to reach the companies' constitutional objections to the advertising restrictions. *Coyne Beahm*, 966 F. Supp. at 1400 n. 33. Because neither party has briefed the First Amendment issue, I do not discuss it here.

⁷ For example, one study cited in the rulemaking record found that "30% of 3-year-olds and 91% of 6-year-olds could identify Joe Camel as a symbol for smoking." *Id.* at 45246 (citing Fischer, Schwartz & Richards, *Brand Logo Recognition by Children Aged 3 to 6 Years, Mickey Mouse and Old Joe the Camel*, Journal of the American Medical Association, 1991).

[by prescription] or upon such other conditions as the Secretary may prescribe in such regulation, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.

The FDA relies on this section as authority for the regulations restricting the advertising of tobacco products, its rationale being that the authority to restrict the "sale" of or to impose "other conditions" on a product includes within it the authority to restrict the means by which such sales are generated.

Examples of obviously permissible restrictions of the "sale" of a product are regulations regarding where, when, by whom, and to whom a product can be sold. But is a restriction on advertising a restriction of the "sale" of a product? The district court found that the plain meaning of the words precluded advertising restrictions: "Both as ordinarily defined and as used in the phrase 'may . . . be restricted to sale, distribution, or use,' the word 'sale' does not encompass the advertising or promotion of a product." *Coyne Beahm*, 966 F. Supp. at 1398 (footnote omitted). But even the dictionary entry cited in the district court's opinion defines "sale" as "the act of selling"; the term "sales" is defined as "[a]ctivities involved in the selling of goods and services." *Id.* at 174 n. 23. Under a *Chevron* step-two analysis—"if the statute is silent or ambiguous with respect to the specific issue, the question is whether the agency's answer is based on a permissible construction of the statute[.]" *Chevron*, 467 U.S. at 843, 104 S. Ct. 2778 (footnote omitted)—we need only find that the

agency construction is a reasonable one, not the best one. See *id.* at 163 n. 11. I believe the term "sale" is ambiguous enough to encompass the concept of "offer for sale."

The district court also distilled an intent to withhold the authority asserted by the FDA from the use of the terms "offer for sale" and "advertising" elsewhere in 1976 legislation. See *Coyne Beahm*, 966 F. Supp. at 1398-99. However, while the "language and design of the statute as a whole" (*K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291, 108 S. Ct. 1811, 100 L.Ed.2d 313 (1988)) might raise a question about the extent of the FDA's authority in this area, it does not mandate a conclusion that Congress intended to foreclose the FDA from imposing advertising restrictions. There is simply no conclusive evidence of intent either way; the phrase is simply ambiguous, both in isolation and with reference to the context in which it is used.

The term "sale, distribution and use," which is used only once in the entire FDCA, can reasonably be construed to include all aspects of a product's journey from the factory to the store and to the home. As I have noted above, tobacco is different from the run-of-the-mine drugs and devices in the FDA's bailiwick, and the nature of the differences dictate new approaches to fight the dangers posed. Because the precise approach chosen might not have been considered by the drafters of the statute does not necessarily preclude it. The interpretation is a reasonable one and, therefore, we must defer to the agency.

V

I would affirm the district court's judgment to the extent that it denies summary judgment to the tobacco companies on the issues of the FDA's authority to regulate tobacco products under the FDCA and to regulate such products as "combination products." I would vacate the judgment below to the extent it grants summary judgment to the companies on the issue of the FDA's authority to regulate the advertising of tobacco products.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
GREENSBORO DIVISION

Nos. 2:95CV00591, 2:95CV00593,
6:95CV00665 and 2:95CV00706

COYNE BEAHM, INC., BROWN & WILLIAMSON
TOBACCO CORPORATION, LIGGETT GROUP, INC.,
LORILLARD TOBACCO COMPANY, PHILIP MORRIS,
INCORPORATED, AND R.J. REYNOLDS
TOBACCO COMPANY, PLAINTIFFS

v.

UNITED STATES FOOD & DRUG ADMINISTRATION
AND DAVID A. KESSLER, M.D.,
COMMISSIONER OF FOOD AND DRUGS, DEFENDANTS

AMERICAN ADVERTISING FEDERATION, AMERICAN
ASSOCIATION OF ADVERTISING AGENCIES,
INC., ASSOCIATION OF NATIONAL ADVERTISERS,
INC., MAGAZINE PUBLISHERS OF AMERICA,
OUTDOOR ADVERTISING ASSOCIATION OF AMERICA,
POINT OF PURCHASE ADVERTISING INSTITUTE,
PLAINTIFFS

v.

DAVID A. KESSLER, M.D., COMMISSIONER
OF FOOD AND DRUGS, AND UNITED STATES
FOOD & DRUG ADMINISTRATION, DEFENDANTS

UNITED STATES TOBACCO COMPANY,
BROWN & WILLIAMSON TOBACCO CORPORATION,
CONWOOD
COMPANY, L.P., NATIONAL TOBACCO
COMPANY, L.P., THE PINKERTON TOBACCO COMPANY,
SWISHER INTERNATIONAL, INC., CENTRAL
CAROLINA GROCERS, INC., J.T. DAVENPORT,
INC., N.C. TOBACCO DISTRIBUTORS COMMITTEE, INC.,
PLAINTIFFS

v.

UNITED STATES FOOD & DRUG ADMINISTRATION
AND DAVID A. KESSLER, M.D.,
COMMISSIONER OF FOOD AND DRUGS, DEFENDANTS

NATIONAL ASSOCIATION OF CONVENIENCE STORES,
ACME RETAIL, INC., PLAINTIFFS

v.

DAVID A. KESSLER, M.D., COMMISSIONER
OF FOOD AND DRUGS, AND UNITED STATES
FOOD & DRUG ADMINISTRATION, DEFENDANTS

[Filed: April 25, 1997]

MEMORANDUM OPINION

OSTEEN, District Judge.

This case comes before the court on Plaintiffs' Motion for Summary Judgment.¹ In August 1996, the Food

¹ For purposes of their motion for summary judgment, Plaintiffs do not dispute the finding of facts made in FDA's

and Drug Administration ("FDA") published in the *Federal Register* "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents" ("Regulations"). 61 Fed. Reg. 44,396 (1996). Plaintiffs now seek summary judgment claiming that Congress has withheld the authority to regulate tobacco products as customarily marketed from FDA and that the Federal Food, Drug, and Cosmetic Act ("FDCA" or "Act")² does not authorize FDA to regulate tobacco products as "drugs" or "devices."

For the reasons discussed herein, Plaintiffs' Motion for Summary Judgment will be granted in part and denied in part.

I. DISCUSSION

A. SUMMARY JUDGMENT PRINCIPLES.

Summary judgment is appropriate in those cases where it is established through pleadings, affidavits, depositions, and other discovery documents that there exists no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48, 106 S. Ct. 2505, 2510, 91 L.Ed.2d 202

jurisdictional determination and preamble to the Regulations. Although FDA did not formally move for summary judgment, it suggests in its Response Brief that the court can and should enter summary judgment in its favor. Since Plaintiffs would contest FDA's factual findings for purposes of a motion by FDA for summary judgment, summary judgment in favor of FDA would not be appropriate.

² 21 U.S.C. § 321 *et seq.*

(1986). Thus, it is the burden of the moving party to show the court that no material factual issues exist for trial. Of course, the court must draw any permissible inference from the underlying facts as established in the record in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587-88, 106 S. Ct. 1348, 1356-57, 89 L.Ed.2d 538 (1986); *Pulliam Inv. Co. v. Cameo Properties*, 810 F.2d 1282, 1286 (4th Cir.1987).

When the moving party has carried its burden, the nonmoving party must come forward with evidence which shows more than some "metaphysical doubt" that genuine and material factual issues exist. *Matsushita*, 475 U.S. at 586, 106 S. Ct. at 1356. A mere scintilla of evidence presented by the nonmoving party is insufficient to circumvent summary judgment. *Anderson*, 477 U.S. at 252, 106 S. Ct. at 2512. Rather, the nonmoving party must convince the court that, upon the record taken as a whole, a rational trier of fact could find for the nonmoving party. *Id.* at 248-49, 106 S. Ct. at 2510-11.

B. CONGRESS HAS NOT WITHHELD JURISDICTION TO REGULATE TOBACCO PRODUCTS FROM THE FOOD AND DRUG ADMINISTRATION.

Plaintiffs assert that Congress clearly intended to withhold jurisdiction to regulate tobacco products from FDA. Plaintiffs urge that the general structure and history of the FDCA and three federal statutes which address tobacco products reveal Congress' intent to reserve to itself the authority to shape federal policy regarding tobacco products and, moreover, that the

Regulations directly conflict with and are precluded by the three congressional tobacco-specific statutes.

The court reviews FDA's construction of the FDCA under the analysis set forth in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 104 S. Ct. 2778, 81 L.Ed.2d 694 (1984). The first responsibility is to determine whether Congress has directly spoken to the precise question at issue for "[i]f the intent of Congress is clear, that is the end of the matter." *Id.* 467 U.S. at 842, 104 S. Ct. at 2781. If, however, the statute "is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* 467 U.S. at 843, 104 S. Ct. at 2782.

1. Congress Expressed No Clear Intent in the Federal Food, Drug, and Cosmetic Act to Withhold Jurisdiction to Regulate Tobacco Products from the Food and Drug Administration.

- a. The Text of the Federal Food, Drug, and Cosmetic Act.

The precise question presented to the court is whether Congress has evidenced its clear intent to withhold from FDA jurisdiction to regulate tobacco products as customarily marketed.³ The inquiry as to

³ Plaintiffs do not dispute that FDA has authority to regulate tobacco products marketed as providing medical or other health benefits. See *United States v. 354 Bulk Cartons Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (D.N.J.1959) (manufacturer claimed in display cards, circulars, and point-of-sale materials that its brand was effective for weight reduction); *United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes*, 113 F.

whether Congress has directly spoken to the issue should begin with an examination of the text of the FDCA.⁴ *Mead Corp. v. Tilley*, 490 U.S. 714, 722, 109 S. Ct. 2156, 2162, 104 L.Ed.2d 796 (1989); *Kofa v. INS*, 60 F.3d 1084, 1088 (4th Cir. 1995). A product is subject to the FDCA if it meets the statute's definition of a "food," "drug," "device," or "cosmetic." See 21 U.S.C. § 321. Rather than itemize each product subject to regulation under the FDCA, Congress defined these categories broadly so that each encompasses a wide range of products.

As will be discussed more fully regarding the second issue raised by Plaintiffs, the court finds that tobacco products fit within the FDCA's definitions of "drug" and "device." Therefore, Plaintiffs must prove to the court that Congress has expressed its clear intent to withhold from FDA jurisdiction to regulate tobacco products in some place other than the text of the FDCA.

Supp. 336 (D.N.J. 1953) (manufacturer promoted the cigarettes through leaflets as effective in preventing certain diseases).

⁴ In support of their assertion that Congress has clearly withheld from FDA jurisdiction over tobacco products, Plaintiffs devote only a small portion of their brief to an examination of the text of the FDCA. Plaintiffs contend that neither the text of the FDCA nor its direct legislative history addresses tobacco products and that the court should, therefore, focus its inquiry on federal legislation that specifically addresses tobacco products. The court will instead first examine the text and legislative history of the FDCA.

b. The Legislative History of the Federal Food, Drug, and Cosmetic Act.

Both parties find support for their arguments in the FDCA's legislative history. Plaintiffs first note that tobacco products not only were highly visible in the years preceding passage of the FDCA, but also were recognized by the federal government as a separate sector of the economy. (Pls.' First Br. Supp. Mot. Summ. J. at 8-9.) Plaintiffs contend that had Congress meant to place such highly visible and controversial products within FDA's jurisdiction, the legislative history of the FDCA would reveal some discussion of the matter. FDA, on the other hand, argues that in its enactment of the FDCA in 1938, Congress broadened the scope of the previous food and drug law, and, despite the high visibility of tobacco products, never excluded them from the FDCA's reach.

Congress passed the first food and drug law, the Pure Food and Drugs Act, in 1906. Pub.L. No. 59-384, 34 Stat. 768 (1906). The 1906 Act defined "drug" to include "all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substances or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals." *Id.* In 1938, Congress passed the FDCA and expanded the definition of "drug" to include articles "intended to affect the structure or function of the body." 21 U.S.C. § 321(g)(1)(C). The House Report accompanying the FDCA explained that the expansion of the definition of "drug" was intended to "amplif[y] and strengthen[]" the FDCA. H.R. Rep. No. 75-2139, at 2 (1938).

In addition to expanding the definition of "drug," Congress added the "device" category to the FDCA in 1938 and included within its definition "instrument[s], apparatus, implement[s], machine[s], contrivance[s], . . . including any component, part, or accessory . . . intended to affect the structure or any function of the body." 21 U.S.C. § 321(h)(3). Congress determined that the "expansion of the definition of the term 'drug' and the inclusion of devices are essential if the consumer is to be protected against a multiplicity of abuses not subject to the present law." S. Rep. No. 74-646, at 1 (1935). Thus Congress, intending to expand the scope of the federal food and drug laws, broadly defined the categories of products to which the FDCA would apply.

In their examination of the legislative history of the FDCA, Plaintiffs focus on the absence of any discussion of tobacco products and assert that although Congress was aware of the possibility of extending FDA's jurisdiction to reach tobacco products, it chose not to. Plaintiffs note that in 1914, FDA's predecessor agency, the Bureau of Chemistry in the Department of Agriculture, expressed its view that it could not regulate tobacco products as customarily marketed under the 1906 Act. Bureau of Chemistry, U.S. Department of Agriculture, *Service & Regulatory Announcements*, No. 13 (Apr. 2, 1914). Plaintiffs also note that in 1929, legislation which would have amended the 1906 Act to cover tobacco products was introduced and referred to the committee on Agriculture and Forestry, but never passed. S. 1468, 71st Cong. (1929). Thus, Plaintiffs contend that Congress was aware of both the highly visible tobacco products and of the possibility of extending jurisdiction under the food and drug laws to cover tobacco products. Plaintiffs conclude that had

Congress contemplated placing tobacco products within the reach of the FDCA, there would have been opposition to, or, at the very least, discussion of the matter. (Pls.' First Br. Supp. Mot. Summ. J. at 9, n. 9.)

The legislative history's silence regarding tobacco products does not indicate that Congress clearly intended to exempt such products from the Act. The FDCA applies to any product which meets one of the broad definitions of the Act, and the absence of discussion of the Act's application to even a highly visible product does not foreclose regulation of that product under the Act. This court is convinced that neither the text nor the legislative history of the FDCA evidences clear congressional intent to withhold from FDA authority to regulate tobacco products.

- c. The Food and Drug Administration's Representations to Congress, Statements of Members of Congress, and Unenacted Legislation.

Plaintiffs contend that FDA's past representations to Congress, the remarks of certain members of Congress, and a series of unenacted bills reveal not only that Congress believed that FDA lacked authority to regulate tobacco products, but also that Congress acquiesced to and ratified that position.

FDA officials testified before congressional committees on numerous occasions that the agency lacked jurisdiction to regulate tobacco products. For example, FDA informed Congress in 1963 that tobacco products as customarily marketed did not meet the definitions in the FDCA for food, drug, device, or cosmetic. See Letter from FDA Bureau of Enforcement (May 23,

1963), reprinted in *Hearings Before the Consumer Subcomm. of the Senate Comm. on Commerce on S. 1454*, 92d Cong., 2d Sess. 240 (1972) ("1972 Hearings"). In 1965, an FDA official testified at a congressional hearing that FDA "has no jurisdiction under the [FDCA] over tobacco, unless it bears drug claims." *Cigarette Labeling and Advertising, Hearing Before the House Comm. on Interstate and Foreign Commerce on H.R. 2248*, 89th Cong. 193 (1965). In 1972, FDA Commissioner Charles Edwards testified that although cigarettes and other tobacco products would be drugs within the meaning of the FDCA if medical claims were made for them, "cigarettes recommended for smoking pleasure are beyond the [FDCA]." *1972 Hearings* at 239. In 1989, FDA Commissioner Frank Young once again conveyed to Congress that "it doesn't look like it is possible to regulate [tobacco] under the [FDCA] even though smoking, I think, has been widely recognized as being harmful to human health." *Hearing Before the Subcomm. on Rural Development, Agriculture, and Related Agencies of the House Comm. on Appropriations*, 100th Cong. 409 (1989).

In addition to expressing its view to Congress that it lacked jurisdiction to regulate tobacco products, FDA defended that position in court. In May 1977, an anti-tobacco group, Action on Smoking and Health ("ASH"), petitioned FDA to regulate cigarettes as "drugs." *Citizen Petition*, Dkt. No. 77P-0185 at 4-11 (May 26, 1977). FDA rejected ASH's petition and the circuit court upheld FDA's decision. See *ASH v. Harris*, 655 F.2d 236 (D.C.Cir.1980). One year later, ASH petitioned FDA to regulate cigarettes as "devices," *Citizen Petition*, Dkt. No. 78P-0338 (Oct. 2, 1978), and FDA rejected ASH's petition. Letter from Acting Com-

missioner Mark Novitch for Commissioner of Food and Drugs to John F. Banzhaf, III, at 3 (November 25, 1980), Dkt. Nos. 77P-0185, 78P-0338/CP.

There is little question that members of Congress agreed with FDA's assertions that it lacked jurisdiction and, in an effort to remedy the situation, introduced numerous bills which would have expressly granted FDA authority to regulate tobacco products. None of the bills passed. *See, e.g.*, H.R. 11280, 84th Cong. (1956); S. 2554, 85th Cong. (1957); H.R. 592, 85th Cong. (1957); S. 1682, 88th Cong. (1963); H.R. 5973, 88th Cong. (1963); H.R. 9512, 88th Cong. (1963); H.R. 2248, 89th Cong. (1965); H.R. 2419, 95th Cong. (1977); H.R. 3879, 95th Cong. (1977); H.R. 7168, 95th Cong. (1977); S. 3317, 95th Cong. (1978); H.R. 279, 96th Cong. (1979); H.R. 3294, 99th Cong. (1987); H.R. 1494, 100th Cong. (1989); S. 769, 100th Cong. (1989). In introducing many of these bills, members of Congress stated that the legislation was needed to give FDA jurisdiction to regulate tobacco products.

Thus, there is evidence not only that FDA previously asserted that it lacked jurisdiction to regulate tobacco products as customarily marketed, but also that some members of Congress agreed with FDA and introduced legislation to expressly grant FDA jurisdiction. Plaintiffs conclude that Congress believed FDA lacked jurisdiction and that its rejection of bills designed to expressly grant FDA such jurisdiction, its amendment of the FDCA without granting such jurisdiction, and its enactment of other tobacco-specific legislation reveal that Congress acquiesced to and ratified FDA's assertion of lack of jurisdiction. The court must first determine whether Congress acquiesced to or ratified FDA's

previous assertions of lack of authority, and, if the court finds that Congress did, determine whether FDA permissibly adapted its position to new evidence.

i. Congress Neither Acquiesced to Nor Ratified the Food and Drug Administration's Position.

The Supreme Court has recognized that unenacted bills generally provide rather unpersuasive evidence of congressional intent. *See Central Bank of Denver v. First Interstate Bank of Denver*, 511 U.S. 164, 187, 114 S. Ct. 1439, 1453, 128 L.Ed.2d 119 (1994) ("[F]ailed legislative proposals are a particularly dangerous ground on which to rest an interpretation of a prior statute.") (internal citations omitted). Further, "the interpretation given by one Congress (or a committee or member thereof) to an earlier statute is of little assistance in discerning the meaning of that statute." *Id.* at 185, 114 S. Ct. at 1452 (quoting *Public Employees Retirement Sys. of Ohio v. Betts*, 492 U.S. 158, 168, 109 S. Ct. 2854, 2861, 106 L.Ed.2d 134 (1989)).

Despite its general reluctance to rely on unenacted bills and statements by members of Congress as evidence of congressional intent, the Supreme Court has held that the rejection of bills by Congress may be relevant to a determination of congressional intent where there are extraordinary circumstances. *See Bob Jones University v. United States*, 461 U.S. 574, 600-02, 103 S. Ct. 2017, 2032-34, 76 L.Ed.2d 157 (1983) (Where "exhaustive hearings" were held on specific issue and "no fewer than 13 bills introduced," Congress' "failure to act" was relevant.); *United States v. Riverside Bayview Homes, Inc.*, 474 U.S. 121, 137, 106 S. Ct. 455, 464, 88 L.Ed.2d 419 (1985) (Congress' failure to act is

relevant "particularly where the administrative construction has been brought to Congress' attention through legislation specifically designed to supplant it."). Plaintiffs contend that FDA's previous assertions that it lacked jurisdiction, Congress' rejection of legislation designed to grant FDA jurisdiction, and the belief of some members of Congress that FDA lacked jurisdiction are extraordinary circumstances which are relevant to a determination of congressional intent. The court is persuaded that the circumstances presented fall short of the extraordinary circumstances found in *Riverside Bayview Homes* and *Bob Jones University*.

In *Riverside Bayview Homes*, the Army Corps of Engineers exercised jurisdiction over wetlands pursuant to the Clean Water Act. Soon thereafter, while considering amendments to the Clean Water Act, Congress specifically considered the regulations. After lengthy debates in both chambers regarding the Corps' assertion of jurisdiction, the Senate version, which did not deny the Corps jurisdiction over wetlands, passed. The House version, however, which denied the Corps jurisdiction, failed to pass. The Court noted that although it would not usually attribute significance to Congress' failure to act, a refusal by Congress to overrule agency construction of a statute, particularly where that construction was brought to the attention of Congress by means of legislation specifically designed to supplant it, was persuasive.

In *Bob Jones University*, the Supreme Court upheld a challenged Internal Revenue Service ("IRS") ruling. Noting congressional failure to modify the ruling despite full awareness of it and refusal to pass 13 bills

which had been introduced to reverse the ruling, the Court stated that Congress had done more than merely fail to act on legislative proposals and had actually acquiesced to the IRS's interpretation. The Court also noted that Congress had affirmatively manifested acquiescence to the policy when it reenacted a version of the section at issue without altering the position taken by the IRS.

Both *Riverside Bayview Homes* and *Bob Jones University* are distinguishable from this case. First, the regulations at issue in *Riverside Bayview Homes* generated a greater response in Congress than did any of FDA's assertions of lack of jurisdiction. Specifically, in *Riverside Bayview Homes*, Congress rejected legislation that would have altered the Corps' regulations and passed legislation that did not alter those regulations only after extensive debate in both chambers. In this case, of the numerous bills introduced to grant FDA jurisdiction over tobacco products, none were reported out of committee. (Defs.' Br. Opp'n Mot. Summ. J. at 36.) Moreover, both *Riverside Bayview Homes* and *Bob Jones University* involved congressional consideration not of an agency's assertion of inability to act, but of agency action. Thus, in both *Riverside Bayview Homes* and *Bob Jones University*, the agency took action,⁵ Congress subsequently considered the matter, and ultimately decided not to invalidate the agency action. In this case, Plaintiffs

⁵ The Army Corps of Engineers promulgated regulations in *United States v. Riverside Bayview Homes, Inc.*, 474 U.S. 121, 106 S. Ct. 455, 88 L.Ed.2d 419 (1985), and the Internal Revenue Service issued rulings in *Bob Jones University v. United States*, 461 U.S. 574, 103 S. Ct. 2017, 76 L.Ed.2d 157 (1983).

urge the court to find that Congress acquiesced not to agency action, but rather to assertions by an agency that it lacked power to act. No case finding congressional acquiescence after an agency's assertion of lack of jurisdiction to act has been cited to the court. The acquiescence argument is less persuasive in this context.

Even if Congress acquiesced to or ratified FDA's prior position that it lacked jurisdiction to regulate tobacco products, the Supreme Court has held that congressional acquiescence to or ratification of agency policy would not necessarily connote approval or disapproval of the agency's later alteration of that policy. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 45, 103 S. Ct. 2856, 2867-68, 77 L.Ed.2d 443 (1983) ("While an agency's interpretation of a statute may be confirmed or ratified by subsequent congressional failure to change that interpretation, . . . even an unequivocal ratification—short of statutory incorporation—of the [agency's interpretation] would not connote approval or disapproval of an agency's later decision to [alter that interpretation]."). Even if Congress acquiesced to FDA's assertion of lack of jurisdiction, such acquiescence would not necessarily connote Congress' opposition to FDA's assertion of jurisdiction.

ii. The Food and Drug Administration May Adapt its Position to New Evidence.

The Supreme Court has held that an agency is entitled to adapt its policies. *See Chevron*, 467 U.S. at 863-64, 104 S. Ct. at 2792 ("An initial agency interpretation is not instantly carved in stone. On the

contrary, the agency, to engage in informed rule-making, must consider varying interpretations and the wisdom of its policy on a continuing basis."). For example, in *Motor Vehicle Mfrs. Ass'n*, 463 U.S. 29, 103 S. Ct. 2856, 77 L.Ed.2d 443, the Court reviewed the Secretary of Transportation's rescission of a requirement that automobiles be equipped with passive restraint systems and held that previous congressional support for the passive restraint requirement did not preclude a change in policy. The Court noted that it "fully recognize[d] that regulatory agencies do not establish rules of conduct to last forever" and that "an agency must be given ample latitude to adapt [its] rules and policies to the demands of changing circumstances." *Id.* at 42, 103 S. Ct. at 2866 (internal citations omitted); *see also Rust v. Sullivan*, 500 U.S. 173, 111 S. Ct. 1759, 114 L.Ed.2d 233 (1991) (Noting that an agency may revise a previous interpretation, the Court rejected the plaintiffs' argument that the challenged regulations were not entitled to deference under the second prong of *Chevron* analysis because they reversed the agency's longstanding interpretation of the statute.); *ASH*, 655 F.2d 236, 242 n. 10 (D.C.Cir.1980) (The court noted, in upholding FDA's denial of jurisdiction to regulate cigarettes, that "[n]othing in this opinion should suggest that [FDA] is irrevocably bound by any long-standing interpretation and representations thereof to the legislative branch. An administrative agency is clearly free to revise its interpretations.").

FDA contends that it has not altered its interpretation of the FDCA but rather has applied its longstanding interpretation to new evidence. As more fully addressed in the court's discussion of the second issue raised by Plaintiffs, the court finds FDA's contention to

be reasonable. *Chevron, Motor Vehicle Mfrs. Ass'n*, and *Rust* support the finding that FDA is entitled to adapt its position in light of new evidence.

Thus, the text of the FDCA, its legislative history, and the body of evidence consisting of FDA's representations to Congress, unenacted bills, and statements by members of Congress do not clearly indicate that Congress intended to withhold from FDA the authority to regulate tobacco products.

2. Congress' Tobacco-Specific Legislation Does Not Reveal that Congress Intended to Withhold Jurisdiction to Regulate Tobacco Products from the Food and Drug Administration.

Plaintiffs assert that Congress has reserved to itself the authority to set federal policy regarding tobacco products. Plaintiffs explain that the structure and history of the Federal Cigarette Labeling and Advertising Act ("FCLAA"),⁶ the Comprehensive Smokeless Tobacco Health Education Act ("CSTHEA"),⁷ and the Alcohol, Drug Abuse, and Mental Health Reorganization Act of 1992 ("ADAMHA Amendments")⁸ reveal Congress' clear intent on the matter. Plaintiffs further urge that conflict between the Regulations and Congress' tobacco-specific legislation supports their argument that Congress clearly reserved to itself the authority to regulate tobacco products. Each statute must be separately addressed.

⁶ 15 U.S.C. §§ 1331-40.

⁷ 15 U.S.C. §§ 4401-08.

⁸ 42 U.S.C. § 300x-26.

a. The Federal Cigarette Labeling and Advertising Act.

Plaintiffs' position is that Congress, believing that FDA lacked jurisdiction to regulate tobacco products, decided to address the concerns raised by tobacco use. Plaintiffs further assert that Congress, in enacting and later amending the FCLAA, expressed its clear intent to shape federal policy regarding tobacco products and to deny FDA a role in implementing that policy. The FCLAA's declaration of policy and purpose states:

It is the policy of Congress, and the purpose of this chapter, to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby—

(1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and

(2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.

15 U.S.C. § 1331. Plaintiffs conclude that this statement of policy evidences Congress' intent to set all federal policy regarding cigarette labeling and advertising.

From a review of only the FCLAA's statement of policy and purpose, Congress arguably intended to preempt any regulation of tobacco products not specifically ordered by Congress. Yet Congress drafted the FCLAA's separate preemption provision very narrowly so as to provide, in relevant part, only that "[n]o statement relating to smoking and health, other than the statement required by section 1333 of this title, shall be required on any cigarette package." 15 U.S.C. § 1334.⁹

The relatively narrow preemptive scope of § 1334 precludes a finding that Congress intended to reserve to itself alone the power to regulate tobacco products. Although § 1331 states that the FCLAA is designed to establish a comprehensive federal program, Congress did not expressly preclude other regulation of tobacco products in § 1334. "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517, 112 S. Ct. 2608, 2618, 120 L.Ed.2d 407 (1992) (discussing preemptive scope of § 1334(b), which addresses federal preemption of state law).

⁹ The court acknowledges that federal-state preemption law does not directly govern the issue of FDA's jurisdiction to regulate tobacco products. Nevertheless, principles from federal-state preemption law apply to the issue of whether Congress has forbidden FDA from regulating tobacco products. Indeed, both the FCLAA and the CSTHEA contain "preemption" sections which specifically address the authority of federal agencies to regulate both cigarettes and smokeless tobacco products, respectively. See 15 U.S.C. §§ 1334, 4406.

Plaintiffs also assert that portions of the FCLAA directly conflict with FDA's assertion of authority. Specifically, Plaintiffs assert that the FCLAA conflicts with the Regulations in the following areas. First, they say that Congress currently permits the manufacture and sale of cigarettes that comply with the FCLAA, and conclude from that fact that Congress in the FCLAA decided that print advertising of tobacco products "should remain lawful, so long as it carries the congressionally-mandated warnings." (Pls.' First Br. Supp. Mot. Summ. J. at 32.) Such conclusion is unwarranted. The fact that Congress has up to this date allowed the manufacture and sale of cigarettes that carry the required warnings does not clearly demonstrate that Congress has determined that no other requirements may be imposed. Congress crafted narrow preemption language in the FCLAA which does not evidence an intention to preclude other regulation of tobacco products. FDA's restrictions on advertising and promotion do not conflict with either the language or the purpose of the FCLAA.

Second, Plaintiffs assert that the Regulations' requirement that cigarette packages state the "established name" of the product (e.g., "cigarette," "cigarette tobacco") and bear the statement "Nicotine-Delivery Device for Persons 18 or Older" is expressly preempted by the FCLAA. FDA agrees that the FCLAA prohibits FDA from requiring packages or advertisements to carry any statement related to smoking and health. FDA argues, however, that the inclusion of the established name merely provides basic information to those coming into contact with the product and that the statement of intended use merely advises consumers about the product's intended use.

According to FDA, neither statement relates to smoking and health within the meaning of § 1334 because neither qualifies as a cautionary statement and that, therefore, neither statement is preempted by the FCLAA.

The Supreme Court addressed the preemptive scope of the FCLAA in *Cipollone*, 505 U.S. 504, 112 S. Ct. 2608, 120 L.Ed.2d 407 (1992). The Court was faced in part with the issue of whether the FCLAA preempted state common law claims of failure to warn. The Court stated that the phrase "No statement relating to smoking and health"

referred to the sort of warning provided for in [§ 1333], which set forth verbatim the warning Congress determined to be appropriate. Thus, on their face, these provisions merely prohibited state and federal rule-making bodies from mandating particular cautionary statements on cigarette labels . . . or in cigarette advertisements. . . .

Id. at 518, 112 S. Ct. at 2618.¹⁰ Neither the statement of intended use nor the established name required by the Regulations is a particular cautionary statement of the type required in § 1333. Thus, neither is expressly preempted by the FCLAA.

The Regulations do not conflict with the text of the FCLAA, and the general structure and purpose of the FCLAA do not evidence Congress' clear intent to

¹⁰ Section 1334(b), rather than § 1334(a), was at issue in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 112 S. Ct. 2608, 120 L.Ed.2d 407 (1992). Nonetheless, the Court's analysis is applicable because the relevant language in the two sections is the same.

withhold jurisdiction from FDA to regulate tobacco products.

b. The Comprehensive Smokeless Tobacco Health Education Act.

Plaintiffs assert that Congress, when it passed the CSTHEA in 1986, reserved to itself the authority to set federal policy regarding smokeless tobacco products. The CSTHEA, like the FCLAA, contains a relatively narrow preemption provision, which provides in relevant part that:

(a) Federal action

No statement relating to the use of smokeless tobacco products and health, other than the statements required by section 4402 of this title, shall be required by any Federal agency to appear on any package or in any advertisement (unless the advertisement is an outdoor billboard advertisement) of a smokeless tobacco product.

15 U.S.C. § 4406. Thus, although the CSTHEA is entitled the *Comprehensive* Smokeless Tobacco Health Education Act, and although Congress addressed in the CSTHEA several of the concerns addressed by FDA in the Regulations, the court finds that Congress did not intend to reserve to itself the exclusive authority to regulate smokeless tobacco products. Rather, the preemptive scope of the CSTHEA is defined by § 4406 because "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted." *Cipollone*, 505 U.S. at 517, 112 S. Ct. at 2618. The narrow effect of

§ 4406 precludes a finding that Congress intended that the CSTHEA preclude all FDA regulation of smokeless tobacco products.

Plaintiffs urge that the CSTHEA expressly preempts the Regulations. Specifically, they contend that FDA's requirement that tobacco products bear a statement of intended use is preempted because the statement relates to the use of smokeless tobacco products and health. The preemption clause of the CSTHEA, like that of the FCLAA, does not preempt FDA's requirement that tobacco products bear both a statement of intended use and the established name of the product.

Thus, the Regulations do not conflict with the text of the CSTHEA, and the general structure and purpose of the CSTHEA do not evidence Congress' clear intent to withhold from FDA jurisdiction to regulate tobacco products.

c. The Alcohol, Drug Abuse, and Mental Health Reorganization Act of 1992.

Plaintiffs assert that Congress' enactment of the ADAMHA Amendments in 1992 evidences Congress' intent to deny FDA jurisdiction over tobacco products. The ADAMHA Amendments withhold federal substance abuse block grants from states that fail to enact and enforce laws prohibiting tobacco sales to minors. Plaintiffs contend that in enacting the ADAMHA Amendments, Congress determined that the initiative for addressing youth access to tobacco products should remain at the state level, and that the appropriate federal role in tackling youth access to tobacco products

is to encourage and help the states in the implementation and enforcement of state policy regarding tobacco products. Plaintiffs further assert that FDA's national program conflicts directly with what Plaintiffs contend is the thrust of the ADAMHA Amendments, which is to place the initiative for development of regulations addressing youth access to tobacco products at state level.

Plaintiffs find that the conflict between the ADAMHA Amendments and the Regulations is clearly demonstrated by the FDCA's preemption provision, which preempts the states from imposing on devices "requirements" that are different from or in addition to those imposed by FDA. 21 U.S.C. § 360k. The argument proceeds that if the FDCA applies to tobacco products, § 360k would prohibit states from addressing the issue of youth access. FDA responds that the Regulations will not affect many aspects of state regulation of underage smoking and that states may qualify for exemptions from the Regulations pursuant to 21 U.S.C. § 360k(b). The Regulations will not prevent states from separately enforcing their own laws regarding underage access or from imposing other restrictions on the access to tobacco products.

Finally, Plaintiffs find in the ADAMHA Amendments a congressional statement of policy regarding tobacco products that is not apparent to the court. The ADAMHA Amendments restructured several federal substance abuse and mental health programs to create two block grants, one directed to drug and alcohol abuse programs, and the other to community mental health services. To receive funds under the substance abuse block grant program, states must conform to a

number of conditions, only a few of which relate to the availability of tobacco products to children under the age of 18.¹¹ The ADAMHA Amendments merely establish conditions for the receipt of federal funds and do not represent an all-encompassing last-word pronouncement of federal policy on underage smoking. The discretionary block grant scheme established by the ADAMHA Amendments does not impliedly preclude further federal requirements regarding tobacco products. Therefore, the court finds that the Regulations conflict with neither the text nor the structure of the ADAMHA Amendments.

Plaintiffs would have the court find from the structure, history, and specific provisions of the FCLAA, the CSTHEA, and the ADAMHA Amendments that Congress clearly intended to reserve to itself, and to withhold from FDA, jurisdiction to regulate tobacco products. Further, Plaintiffs say that the three statutes, working together, comprise Congress' comprehensive policy regarding tobacco products. These conclusions are not justified. Congress, in enacting and later amending the three statutes, adopted narrow preemption language, evidencing its intent not to prohibit other agency action in the area. Moreover, the court cannot find, as Plaintiffs urge, that the three

¹¹ The conditions relating to underage access restrictions provide that states must: (i) prohibit sales to children under 18; (ii) enforce that prohibition "in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18"; (iii) conduct annual random, unannounced inspections of tobacco retailers; and (iv) make annual reports to the Department of Health and Human Services concerning the method and effects of the state enforcement efforts. 42 U.S.C. § 300x-26.

statutes, construed together, evidence Congress' clear intent to withhold from FDA jurisdiction to regulate tobacco products.¹²

In conclusion, the FDCA, the FCLAA, the CSTHEA, and the ADAMHA Amendments do not reveal that Congress clearly intended to withhold from FDA authority to regulate tobacco products.

¹² The court is not presented with a situation similar to that in *International Bhd. of Teamsters v. Daniel*, 439 U.S. 551, 99 S. Ct. 790, 58 L.Ed.2d 808 (1979). The issue in *International Bhd. of Teamsters* was whether the Securities Exchange Act ("SEA"), as asserted by the Securities and Exchange Commission ("SEC"), appearing as *amicus*, applied to noncontributory compulsory pension plans. The Court noted that the Employee Retirement Income Security Act ("ERISA"), which was enacted after the SEA, constituted comprehensive legislation governing the use and terms of employee pension plans and found that Congress had enacted ERISA in order to fill the regulatory gap that had been created regarding pension plans. The Court noted that SEC had never before interpreted the SEA to apply to noncontributory compulsory pension plans and found that SEC's new interpretation was precluded by the later comprehensive ERISA. As explained above, the FCLAA, the CSTHEA, and the ADAMHA Amendments, unlike ERISA, do not create a comprehensive federal approach to the regulation of tobacco products, making this case distinguishable from *International Bhd. of Teamsters*.

C. THE FOOD AND DRUG ADMINISTRATION MAY REGULATE TOBACCO PRODUCTS PURSUANT TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

Plaintiffs assert that tobacco products do not fall within the FDCA's definitions of "drug" and "device." Plaintiffs further assert that FDA misapplied the provisions of the FDCA to tobacco products, and that FDA's misapplication of the Act further demonstrates that FDA lacks jurisdiction to regulate tobacco products under the FDCA. The court's responsibility is to determine whether tobacco products fit within the FDCA's definitions of "drug" and "device" and then to examine FDA's application of the Act to tobacco products.

1. Tobacco Products Fall Within the "Drug" and "Device" Definitions of the Federal Food, Drug, and Cosmetic Act.

The FDCA defines "drug" and "device," in relevant part, as follows:

The term "drug" means . . . (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals.

21 U.S.C. § 321(g)(1).

The term "device" . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

. . . .

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

21 U.S.C. § 321(h).¹³

¹³ The court will refer to §§ 321(g)(1)(C) and (h)(3) as the "structure-or-function" definitions of "drug" and "device," respectively, and to §§ 321(g)(1)(B) and (h)(2) as the "treatment-of-disease" definitions of "drug" and "device," respectively. The court includes the treatment-of-disease definition because of its relevance to the court's discussion of the meaning of intended use. Specifically, since both definitions refer to the intended use of a product, both are relevant to the court's interpretation of the phrase.

FDA offers that tobacco products fall within the FDCA's definitions of "drugs" and "devices" because they are "intended to affect the structure or any function of the body." FDA explains that the nicotine in tobacco products affects the structure or function of the body by causing and sustaining addiction and by acting as a stimulant, sedative, and weight regulator. FDA further argues that manufacturers intend nicotine to produce such effects. Plaintiffs disagree, claiming that tobacco products neither "affect the structure or any function of the body" nor are intended to affect the structure or function of the body within the meaning of the FDCA.

a. Tobacco Products' Effects are "Intended" Within the Meaning of the Federal Food, Drug, and Cosmetic Act.

Plaintiffs claim that a product's "intended use" can be established only by manufacturer representations about the product.¹⁴ FDA counters that it appropriately relied on evidence of foreseeability, consumer use, and internal manufacturer memoranda to establish intended use. The text, legislative history, and past judicial and agency interpretation of the structure-or-function definitions of "drug" and "device" reveal that intended use may be established by evidence other than manufacturer representations.

¹⁴ FDA does not contend that tobacco manufacturers make any representations in connection with the sale of tobacco products. Therefore, if intended use can be established only by manufacturer representations, tobacco products would not be subject to regulation pursuant to the FDCA.

Since the FDCA does not define "intend," the court must give the term its ordinary meaning. See *Asgrow Seed Co. v. Winterboer*, 513 U.S. 179, 187, 115 S. Ct. 788, 793, 130 L.Ed.2d 682 (1995) ("When terms used in a statute are undefined, we give them their ordinary meaning."). FDA directs the court to two definitional sources. First, a dictionary defines "intend" as "[t]o have in mind; plan.... [t]o design for a specific purpose. . . . [t]o have in mind for a particular use." *The American Heritage Dictionary* 668 (2d ed.1991). Second, according to FDA, the court should consider the legal usage of "intend," which includes the principle that one intends the readily foreseeable consequences of his actions. See *Agnew v. United States*, 165 U.S. 36, 53, 17 S. Ct. 235, 242, 41 L.Ed. 624 (1897) ("The law presumes that every man intends the legitimate consequences of his own acts."). From this definition and usage, the plain meaning of "intend" does not indicate that intent must be proven by any particular kind of evidence. In addition, the text of the structure-or-function and the treatment-of-disease definitions does not limit the type of evidence upon which FDA may rely to establish intended use. Indeed, Plaintiffs have made no attempt to argue that the text of the FDCA supports their position that only manufacturer representations can establish intended use. It is clear that the plain language of the structure-or-function definition does not prohibit consideration of evidence other than manufacturer representations in determining a product's intended use. Since, however, the text does not disclose the types of evidence upon which FDA may rely to establish intended use, it is necessary to examine the relevant legislative history.

Plaintiffs assert that the legislative history of the phrases "intended to affect" and "intended for use" is unambiguous and, furthermore, supports their argument that intended use must be established by manufacturer representations. (Pls.' Second Br. Supp. Mot. Summ. J. at 8.) First, Plaintiffs note the following section of a Senate Report which addresses the method of determining whether a product would, for example, meet the Act's "food" or "drug" definitions:

The use to which the product is to be put will determine the category into which it will fall. . . . The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put.

S. Rep. No. 74-361, at 4 (1935); *see also* S. Rep. No. 73-493, at 111-12 (1934) (same). This statement is not unambiguous, and, moreover, does not clearly support Plaintiffs' position. The first sentence is consistent with FDA's position that the use of the product can establish intended use. In addition, the second sentence does not reveal that Congress intended to limit the types of evidence that could be relied on to establish intended use. Indeed, Congress' use of "can" rather than "will" arguably shows that Congress did not intend for manufacturer representations to provide the only evidence of intended use.

Second, Plaintiffs cite to testimony of FDA Chief Campbell in which he explained that an ordinary product, such as a lamp, would be subject to FDA's jurisdiction if, for example, it were marketed as a cure for blindness. Testimony on S. 2800, 73d Cong., at 518

(1934). Plaintiffs conclude that this legislative history clearly reveals that both Congress and FDA understood that FDA's jurisdiction "was limited to products *represented* to provide medical or other health benefits." (Pls.' Second Br. Supp. Mot. Summ. J. at 9.) As mentioned above regarding the first issue, the court should be and is unable to conclude from the testimony of one FDA representative to a congressional committee that Congress expressly incorporated that person's understanding of the bill into the final legislation. In any event, these two pieces of legislative history are not "unambiguous" and, moreover, do not clearly show that Congress intended FDA to rely exclusively upon evidence of manufacturer representations to establish intended use.

Plaintiffs find support for their interpretation of "intended use" in prior judicial construction of the phrase and reason that courts have construed the FDCA to require evidence of manufacturer representations to establish intended use. Although it is true that no court has ever found that a product is "intended for use" or "intended to affect" within the meaning of the FDCA absent manufacturer claims as to that product's use, no court has held that intended use can be established solely by promotional representations. Furthermore, courts have acknowledged, albeit *in dicta*, that FDA may rely on other types of evidence to establish intended use. *United States v. Article of 216 Cartoned Bottles*, "Sudden Change," 409 F.2d 734, 739 (2d Cir. 1969) ("It is well settled that the intended use of a product may be determined from its label, accompanying labeling, promotional material, advertising and any other relevant source."); *ASH v. Harris*, 655 F.2d 236, 239 (D.C. Cir. 1980) (In the absence of promotional

claims, FDA would need to make a substantial showing of evidence of consumer use to justify an inference as to vendor intent.); *National Nutritional Foods Ass'n v. FDA*, 504 F.2d 761, 789 (2d Cir.1974) (In considering whether high potency vitamins sold without therapeutic representations are drugs, FDA is "free to pierce . . . a manufacturer's . . . misleadingly 'nutritional' labels to find actual therapeutic intent on the basis of objective evidence."); *United States v. 250 Jars U.S. Fancy Pure Honey*, 218 F.Supp. 208, 211 (E.D. Mich. 1963) (To find intended use, a "court is not limited to the labels on such article or to the labeling which accompanies it, but may look at all relevant sources."), *aff'd*, 344 F.2d 288 (6th Cir. 1965); *United States v. Ten Cartons Ener-B Vitamin B-12*, 72 F.3d 285, 287 (2d Cir.1995) (An article can be a drug under 21 U.S.C. § 321(g)(1)(C) for reasons other than claims made in the label or labeling, such as "method of intake."). Certainly, courts have recognized that evidence other than manufacturer claims could be used to establish intended use within the meaning of § 321(h)(3).

Finally, Plaintiffs argue that FDA's own regulations require evidence of manufacturer representations to establish intended use. See 21 C.F.R. §§ 201.128, 801.4 (defining "intended use" regarding drugs and devices, respectively).¹⁵ Although the regulations defining "in-

¹⁵ 21 C.F.R. §§ 201.128 and 801.4 provide, in relevant part, that:

The words "intended uses" or words of similar import . . . refer to the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such

tended use" clearly anticipate the establishment of intended use through evidence of promotional claims, the plain language does not prohibit the establishment of intended use by other evidence. To illustrate, the regulations specifically provide that intent may be shown by circumstances surrounding the sale of the article and that one such circumstance could be the offering and use of a product for a purpose for which it is neither advertised nor labeled with the manufacturer's knowledge. The regulations defining "intended use" do not prohibit reliance on evidence other than manufacturer representations to establish intended use.

The plain language and the legislative history of the drug and device definitions do not reveal that Congress clearly intended for FDA to rely only upon evidence of manufacturer representations to establish intended use. In addition, past judicial and agency construction of the definitions does not foreclose consideration by FDA of

persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.

other evidence to establish intended use. Even so, the court must still determine whether FDA properly relied upon evidence of foreseeability, actual consumer use, and internal manufacturer memoranda to establish intended use.

i. Foreseeable Use.

Although the text of the "drug" and "device" definitions does not expressly state that FDA may consider evidence of foreseeability to establish intended use, nothing in the text or the legislative history of the FDCA prohibits consideration of such evidence. Thus, Congress has not expressed a clear intent regarding whether FDA may consider evidence of foreseeability to establish intended use within the meaning of the FDCA and, finding FDA's interpretation to be reasonable, this court will defer to it. See *Chevron*, 467 U.S. at 845, 104 S. Ct. at 2783 ("Once [the court] determine[s], after its own examination of the legislation, that Congress did not actually have an intent regarding [the issue], the question before it [is] . . . whether the [agency's] view . . . is a reasonable one.").

ii. Actual Consumer Use.

Plaintiffs assert that FDA may not rely on evidence of actual use to establish intended use within the meaning of the FDCA. Nothing in the text or legislative history of the FDCA prohibits consideration of actual use to establish intended use. Indeed, one House Report expressly contemplates reliance upon such evidence. See H.R.Rep. No. 94-853, at 14 (1976) (FDA may consider "actual use of a product in determining whether or not it is a device."); see also *United States v.*

22 Devices "*The Ster-O-Lizer MD-200*", 714 F. Supp. 1159, 1165 (D. Utah 1989) (Objective intent may be shown "not only by a product's labeling claims, advertising or written statements relating to the circumstances of a product's distribution, but also by a product's actual use.") (internal citations omitted). Moreover, although no court has expressly held that intended use may be established by evidence of actual use, no court has ever prohibited reliance on such evidence. Some courts have even noted *in dicta* that evidence of consumer use may establish intended use within the meaning of the FDCA. See *ASH v. Harris*, 655 F.2d 236, 240 (D.C. Cir. 1980) (If consumers "use the product predominantly—and in fact nearly exclusively—with the appropriate intent . . . [,] the requisite statutory intent can be inferred."); *National Nutritional Foods Ass'n v. Weinberger*, 512 F.2d 688, 703 (2d Cir. 1975) (intended use under the treatment-of-disease definition could possibly be inferred from evidence of near exclusive consumer use). Other courts have also noted in dicta that evidence of manufacturer intent can be corroborated by evidence of consumer use. See *United States v. Kasz Enterprises, Inc.*, 855 F. Supp. 534, 539 (D. R.I. 1994) (Intended use "can be demonstrated by . . . evidence that the vendor is aware that his product is being offered or used by others for a purpose for which it is neither labeled nor advertised."), modified on other grounds, 862 F. Supp. 717 (D.R.I. 1994); *United States v. 789 Cases Latex Surgeons' Gloves*, 799 F. Supp. 1275, 1285, 1294-95 (D. P.R. 1992) (intended use determined by all the facts, including "actual use"); *United States v. Two Plastic Drums*, 761 F. Supp. 70, 72 (C.D. Ill. 1991) ("[A] court should examine a wide range of evidence, including . . . actual use of the product."), *aff'd*, 984 F.2d 814 (7th

Cir.1993). Still other courts have expressly relied on actual use as a factor contributing to the establishment of intended use. See *United States v. An Article of Device Toftness Radiation Detector*, 731 F.2d 1253, 1257 (7th Cir. 1984) (intended use established in part by witness testimony that device had been used to treat patients); *United States v. 22 Devices "The Ster-O-Lizer MD-200"*, 714 F. Supp. at 1165 (court noted that the product was used in the surgical treatment of patients); *United States v. Device Labeled "Cameron Spitler Amblyo-Syntonizer"*, 261 F. Supp. 243, 245 (D. Neb. 1966) (although claimant contended that no representations had been made about the product, he admitted the use of the product).

Again, the FDCA does not reveal that Congress clearly intended to permit or prohibit reliance on evidence of actual use to establish intended use. Finding FDA's determination that it may consider evidence of actual use to establish intended use to be reasonable, especially in light of judicial recognition of the possibility, the court will defer to FDA's interpretation. See *Chevron*, 467 U.S. at 845, 104 S. Ct. at 2783 ("Once [the court] determine [s], after its own examination of the legislation, that Congress did not actually have an intent regarding [the issue], the question before it [is] . . . whether the [agency's] view . . . is a reasonable one.").

iii. Statements, Knowledge, and Action of Manufacturers.

Plaintiffs assert that FDA may not establish intended use based on evidence of the subjective intent of manufacturers. As previously discussed in the sections

regarding evidence of foreseeability and actual use, neither the text nor the legislative history of the FDCA reveals Congress' clear intent to prohibit consideration of such evidence. The court agrees, however, that FDA's own regulations defining "intended use" provide that intended use may be established only by evidence of objective intent. See 21 C.F.R. §§ 201.128, 801.4 ("The words 'intended uses' or words of similar import . . . refer to the objective intent of the persons legally responsible for the labeling of drugs."). Nonetheless, since FDA found that each of the three types of evidence upon which it relied provided independent bases for finding intended use within the meaning of the Act, 61 Fed. Reg. at 44,632-33, the court concludes that FDA adequately and properly supported its finding of intended use with evidence of foreseeability and consumer use.

b. Tobacco Products Affect the Structure or Function of the Body Within the Meaning of the Federal Food, Drug, and Cosmetic Act.

Plaintiffs infer that Congress intended for the structure-or-function definition of device to "apply only to products that are marketed to provide some medical or other health benefit to users." (Pls.' Second Br. Supp. Mot. Summ. J. at 5.) They support their argument in part by noting that Congress entitled its 1976 amendments to the FDCA's device provisions the "Medical Device Amendments" ("MDA"). The definition of device, however, expressly includes those products "intended to affect the structure or any function of the body of man or other animals" and gives no indication that it is to apply only to those devices with a medical purpose. 21 U.S.C. § 321(h). The plain language of the

structure-or-function definition of "device" does not limit the statute's reach to only those devices with a medical purpose.

Neither does the legislative history indicate that Congress intended to limit the scope of the structure-or-function definition to apply only to devices with a medical purpose. Congress included the structure-or-function definition in the FDCA in 1938. Nothing in the legislative history of the 1938 Act specifically addresses the meaning of the phrase "intended to affect the structure or any function of the body." Congress did explain that the FDCA was intended to broaden the scope of the older food and drug laws to reach, among other things, "therapeutic devices." *See* H.R.Rep. 75-2139, at 2 (1938). The legislative history of the MDA also reveals some discussion of the general purpose of the device provisions. For example, the Senate Report accompanying the MDA states that "[i]ncreasing numbers of patients have been exposed to increasingly complex devices which pose serious risk if inadequately tested or improperly designed or used" and that FDA lacked the tools under the FDCA to adequately regulate such devices. S.Rep. No. 94-33 (1976) U.S. Code Cong. & Admin. News 1976 p. 1070. It also notes that Congress recognized the need for "regulation to assure that the public is protected and that health professionals can have more confidence in the performance of devices." *Id.* The Report further states that the medical device legislation was "intended to assure that medical devices . . . meet the requirements of safety and effectiveness before they are put in widespread use throughout the United States." *Id.*

Consequently, the legislative history of the structure-or-function definition of "device" suggests that Congress was concerned about the lack of regulation of devices that posed a danger to the public. Although Congress clearly intended that the FDCA apply to devices used within the medical community, nothing in the legislative history indicates that Congress intended to limit the FDCA's reach to devices offered for beneficial or therapeutic purposes. The fact that Congress contemplated the Act's application to certain medical devices does not foreclose application of the Act to other devices, especially where the text does not preclude such application.

Finally, Plaintiffs urge the court to narrowly construe the structure-or-function definition of device, claiming that acceptance of FDA's regulation of non-therapeutic devices could result in FDA regulating almost anything that can be said to affect the structure or function of the body. This argument lacks merit. *See United States v. Sullivan*, 332 U.S. 689, 694, 68 S. Ct. 331, 335, 92 L.Ed. 297 (1948) ("The scope of the [statute] . . . is not to be judicially narrowed . . . by envisioning extreme possible applications. . . . There will be opportunity enough to consider such contingencies should they ever arise.").

The four corners of the text and the legislative history of the structure-or-function definition of device do not reveal the clear intent of Congress to include only medical or therapeutic devices within the jurisdiction of the FDCA. FDA's application of the FDCA to non-therapeutic devices is reasonable and entitled to deference from the court. *See Chevron*, 467 U.S. at 845, 104 S. Ct. at 2783 ("Once [the court] determine[s], after

its own examination of the legislation, that Congress did not actually have an intent regarding [the issue], the question before it [is] . . . whether the [agency's] view . . . is a reasonable one.”).

2. The Food and Drug Administration May Regulate Tobacco Products as Medical Devices Pursuant to its Device Authorities.

FDA determined that tobacco products are combination products consisting of the drug nicotine and device components which are intended to deliver nicotine to the body. FDA elected to regulate tobacco products pursuant to its device authorities. Plaintiffs argue that FDA has both contorted and evaded the FDCA and that FDA's application of the Act confirms Plaintiffs' assertion that the FDCA's device provisions “simply do not fit tobacco products.” (Pls.' Second Br. Supp. Mot. Summ. J. at 47.) The court must first determine whether tobacco products are combination products within the meaning of the FDCA and then ascertain whether FDA has applied the Act to tobacco products in a permissible manner.

a. Tobacco Products are Combination Products Within the Meaning of the Federal Food, Drug, and Cosmetic Act.

Plaintiffs assert that tobacco products are not combination products within the meaning of the Act for three reasons. First, Plaintiffs urge that “a combination product must consist of two products, each of which could be *separately* regulated” and that tobacco products do not meet that definition. (Pls.' Second Br. Supp. Mot. Summ. J. at 29.) FDA responds that a

combination product consists of a combination of a drug, device, and/or biological product, and that the total product need only contain components that meet two of those definitions.

The FDCA does not separately define “combination product,” stating only that a combination product is a product “that constitute[s] a combination of a drug, device, or biological product.” 21 U.S.C. § 353(g)(1). The plain language of the definition, therefore, does not reveal whether it was Congress' intention that each component be subjected separately to regulation.¹⁶

¹⁶ FDA's regulations define “combination product” to include:

(1) A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

(2) Two or more separate products packaged together in a single package or as a unit and comprised of drugs and device products, device and biological products, or biological and drug products;

(3) A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or

(4) Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Since Congress has not expressed its intent regarding whether combination products must be comprised of two separately regulable products, and since FDA's interpretation is reasonable, the court should and will uphold that interpretation. *See Chevron*, 467 U.S. at 845, 104 S. Ct. at 2783 ("Once [the court] determine[s], after its own examination of the legislation, that Congress did not actually have an intent regarding [the issue], the question before it [is] . . . whether the [agency's] view . . . is a reasonable one.").

Second, Plaintiffs contend that the device component of tobacco products does not meet the definition of "device" because it does not itself affect the structure or function of the body. FDA responds that the device component need only have an indirect effect on the structure or function of the body to meet the definition of "device." The plain language of the structure-or-function definition does not preclude FDA's interpretation. Additionally, FDA has regulated as devices products that do not themselves directly affect the structure or function of the body, but instead deliver to the body an agent or substance that has such a direct effect. *See, e.g.*, 21 C.F.R. § 878.4635 (ultraviolet lamps

(f) Device has the meaning given the term in [21 U.S.C. § 321(h)].

(g) Drug has the meaning given the term in [21 U.S.C. § 321(g)].

21 C.F.R. § 3.2.

FDA avows that it routinely regards the following products as combination products: pre-filled delivery systems, such as pre-filled syringes, intravenous infusion pumps, nebulizers, metered dose inhalers, and nicotine patches. 61 Fed. Reg. at 45,211.

that deliver ultraviolet light which causes tanning); 21 C.F.R. § 878.4800 (surgical stapler that delivers staples that affect body tissues by holding them together); 21 C.F.R. § 880.5475 (jet lavage that delivers sterile fluid that cleans wounds); 21 C.F.R. § 880.5570 (hypodermic needle that delivers drug substance to site on body); 21 C.F.R. § 868.5580 (oxygen mask that delivers oxygen for absorption by the lungs).

Nothing in the text nor the history of the FDCA suggests that a product must directly, rather than indirectly, affect the structure or function of the body to be subject to regulation under the Act. Furthermore, FDA's interpretation is reasonable. *See Chevron*, 467 U.S. at 845, 104 S. Ct. at 2783 ("Once [the court] determine[s], after its own examination of the legislation, that Congress did not actually have an intent regarding [the issue], the question before it [is] . . . whether the [agency's] view . . . is a reasonable one.").

Third, Plaintiffs protest that tobacco products have no device components within the meaning of the Act because they fall within an explicit exception of the device definition. The FDCA excludes from the definition of "device" a product "which . . . achieve[s] its primary intended purposes through chemical action within or on the body of man or other animals and which is . . . dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h)(3). FDA has found that the primary mode of action of tobacco products is that of a drug. 61 Fed. Reg. at 44,400-03, 45,209-18. Plaintiffs conclude that, under FDA's own analysis, tobacco products achieve their primary intended purposes through chemical action within or on the body of man and

depend upon being metabolized for the achievement of their primary intended purposes.

FDA responds that it found tobacco products to be combination products and that, although a device or device component cannot achieve its primary purpose by chemical action within or on the body under the Act, a combination product consisting of a drug and a device may. FDA further contends that the device component of tobacco products does not rely on chemical actions within or on the body to achieve its primary function and thereby is not excluded from the device definition. FDA has found that the device component of cigarettes consists of the tobacco blend, filter, and cigarette ventilation system, and that the device component of smokeless tobacco consists of the processed tobacco, and, in some products, the pouch. FDA states that the primary function of the device component of cigarettes is to "release a nicotine-containing aerosol, i.e., the tobacco smoke, that, upon combustion outside the body, is inhaled by the smoker and serves as a vehicle for nicotine delivery." 61 Fed.Reg. at 45,209. FDA claims that the primary function of the device component of smokeless tobacco is to "deliver the nicotine to the cheek and gum tissue for absorption," 61 Fed.Reg. at 45,213, and, where the porous pouch is used, to "hold[] the processed tobacco in position in the mouth, controlling the absorption of nicotine into the buccal mucosa." 61 Fed.Reg. at 45,214.

The court finds that the device components of tobacco products fully satisfy the device definition even though the drug component achieves its primary intended purpose through a series of chemical actions inside the body.

b. The Food and Drug Administration May Regulate Tobacco Products Pursuant to its Device Authorities.

Upon determination that tobacco products' primary mode of action is that of a drug, FDA, in accordance with 21 U.S.C. § 353(g),¹⁷ assigned to the agency's Center for Drug Evaluation and Research ("CDER") the responsibility of premarket review. FDA also directed CDER to apply the Act's device provisions because FDA thought that regulation of tobacco products as devices "is the available option that is the most consistent with both the [A]ct and the agency's mission to protect the public health." 61 Fed.Reg. at 44,398.

Plaintiffs contend that once FDA determined that the primary mode of action of tobacco products is that

¹⁷ 21 U.S.C. § 353(g) provides, in relevant part, that:

(g) Combinations of drugs, devices, or biological products

(1) The Secretary shall designate a component of the [FDA] to regulate products that constitute a combination of a drug, device, or biological product. The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

(A) a drug (other than a biological product), the persons charged with premarket review of drugs shall have primary jurisdiction,

(B) a device, the persons charged with premarket review of devices shall have primary jurisdiction,

....

(2) Nothing in this subsection shall prevent the Secretary from using any agency resources of the [FDA] necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article.

of a drug, FDA lacked discretion to regulate them pursuant to its device, rather than its drug, authorities. As Plaintiffs note, the distinction between "drug" and "device" has legal and practical significance because different regulatory schemes apply to each. Plaintiffs assert that, just as FDA lacks discretion to regulate what it deems to be a "drug" pursuant to its device authorities or to regulate what it deems to be a "device" pursuant to its drug authorities,¹⁸ it lacks discretion to choose which authorities to apply to combination

¹⁸ In the Medical Device Amendments of 1976 ("MDA"), Congress amended the "device" definition to provide that a device "does not achieve its primary intended purposes through chemical action within or on the body of man . . . and which is not dependent upon being metabolized for the achievement of its primary intended purposes." The reports accompanying the MDA suggest that Congress amended the definition to draw a clearer line between the "drug" and "device" definitions at least in part in response to the Supreme Court's decision in *United States v. An Article of Drug Bacto-Unidisk*, 394 U.S. 784, 89 S. Ct. 1410, 22 L.Ed.2d 726 (1969). See H.R.Rep. No. 94-853 (1976); S. Rep. No. 94-33 (1975). *Bacto-Unidisk* involved a challenge to FDA's decision to regulate a product as a drug, rather than as a device. FDA wanted to subject the product to premarket review, but, at that time, lacked authority to subject a device to premarket review. Thus, FDA tried to regulate the product as a drug. The Supreme Court upheld FDA's actions, noting that the statute was of little assistance in determining precisely what differentiated a "drug" from a "device." The House and Senate Reports indicate that Congress amended the "device" definition to clarify the distinction between "drugs" and "devices" and to assist FDA in avoiding entanglement in legal battles. *Id.* Although Plaintiffs interpret the legislative history of the MDA as indicating that Congress intended to limit FDA's discretion to choose regulatory authorities, the court interprets the legislative history as primarily revealing Congress' concern that FDA's device authority was deficient and its intent to enhance those authorities. *Id.*

products. Although it is clear to the court that FDA may not regulate as a "device" a product that meets only the definition of "drug," the question remains how FDA is to regulate a product that contains both drug and device components and thereby meets the definition of a combination product under the Act.

Section 353(g), the only provision of the FDCA relevant to the regulation of combination products, provides that FDA must determine the primary mode of action of a combination product, and that FDA's determination directs the regulatory path by which FDA conducts premarket review of the product. FDA contends that a product need not be regulated pursuant to FDA's drug authorities merely because the CDER has primary jurisdiction for premarket review of the product.

FDA's interpretation of § 353(g) is not prohibited by the plain language of the section. The section merely provides that, for example, the persons charged with premarket review of drugs shall have primary jurisdiction over combination products whose primary mode of action is that of a drug. Thus, the text of § 353(g) does not reveal whether Congress intended for FDA to have discretion to regulate a combination product pursuant to the authority of its choice.

The legislative history of § 353(g) provides little guidance regarding Congress' intent. Congress included the combination product provision in the Safe Medical Devices Act ("SMDA") of 1990. The Senate Report states that:

The Committee is aware of the difficulty under the present law in determining the jurisdictional basis for regulating products that are comprised of combinations of drugs, devices, or biologics. This provision will provide the Secretary with firm ground rules to direct products promptly to that part of the FDA responsible for reviewing the article that provides the primary mode of action of the combination product. Various persons from industry have expressed the view that a weakness in FDA's premarket review process is the determination of how to regulate combination products. This provision should assist the Secretary in avoiding delays in making that determination, and is important since more combination products are coming before the agency for premarket review

....

S. Rep. No. 101-513, 101st Cong., 2nd Sess. (1990). The House Conference Report refers to § 353(g) as describing the "general procedures for determining the appropriate component of the FDA to review premarket submissions for products that are comprised of any combination of drugs, devices, or biologics." H.R. Conf. Rep. No. 101-959, at 29 (1990). The court does not find in this legislative history the clear intent of Congress that FDA apply its drug authorities to combination products whose primary mode of action is that of a drug and its device authorities to combination products whose primary mode of action is that of a device.

The court finds that Congress has not expressed any intent as to whether FDA has discretion to apply the regulatory authority of its choice to combination pro-

ducts. The court acknowledges that FDA may not apply the regulatory authority of its choice to non-combination products. On the other hand, the court notes that Congress may have intended for FDA, with its expertise, to apply what it deemed to be the most appropriate regulatory authority to different combination products.¹⁹ In any event, absent any guidance from Congress, the court is constrained by the principles of statutory construction set forth in *Chevron*. Thus, although the court hesitates to agree with FDA that the agency has unfettered discretion to apply the regulatory authority of its choice to combination products, the court finds that the intent of Congress is not clear and, finding FDA's interpretation to be at least reasonable, defers to FDA's interpretation. See *Chevron*, 467 U.S. at 845, 104 S. Ct. at 2783 ("Once [the court] determine[s], after its own examination of the legislation, that Congress did not actually have an intent regarding [the issue], the question before it [is] . . .

¹⁹ FDA notes that, shortly following passage of the Safe Medical Devices Act ("SMDA") in 1990, it adopted implementing regulations and delegations of authority which reflect its contemporaneous interpretation of the SMDA as authorizing it to apply the most appropriate regulatory authorities to any given combination product. See 61 Fed.Reg. at 44,402-03. In addition, FDA notes that it has previously exercised discretion to apply what it considered to be the most appropriate regulatory authority to a combination product when it regulated the intravenous infusion pump as a device. An intravenous infusion pump is a drug delivery device which consists of a device (the pump) and a drug (the diluent) and which is designed to be sold prefilled. FDA states that it exercised its discretion to regulate intravenous pumps as devices because whereas the agency was familiar with the drug component of the product, it was not familiar with the device component which was new and raised significant regulatory questions. See 61 Fed.Reg. at 44,403.

whether the [agency's] view . . . is a reasonable one.").

3. Portions of the Food and Drug Administration's Restrictions are Not Authorized Under the Federal Food, Drug, and Cosmetic Act's Device Authorities.

The court has found that FDA properly regulated tobacco products pursuant to its device authorities. The question remains whether FDA has properly applied its device authorities to tobacco products. The Regulations' requirements fall into essentially three categories: restrictions on advertising and promotion,²⁰ restrictions on access,²¹ and labeling requirements.²² FDA promulgated the first two categories of restrictions pursuant to 21 U.S.C. § 360j(e), and the last pursuant to 21 U.S.C. § 352. The court will address each category of restrictions in turn.

²⁰ The promotional and advertising restrictions limit certain advertising to a black-and-white text-only format, restrict the trade or brand name of certain tobacco products, prohibit the sale or distribution of brand-identified promotional non-tobacco items such as hats and tee shirts, and prohibit use of a brand name of a tobacco product to sponsor entries, teams, sporting and other events.

²¹ The access restrictions prohibit the sale of tobacco products to individuals under the age of 18, require retailers to verify a purchaser's age by photographic identification, prohibit the sale of tobacco products through vending machines and self-service displays except in facilities where individuals under the age of 18 are not permitted, prohibit distribution of free samples, and prohibit the sale of cigarette packages containing fewer than 20 cigarettes.

²² FDA requires tobacco product packages, cartons, and boxes to bear the established name of the product and a statement of intended use.

- a. Section 360j(e) Does Not Authorize Restrictions on the Promotion and Advertisement of Tobacco Products.

Section 360j(e), entitled "Restricted devices," provides:

(1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use—

(A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or

(B) upon such other conditions as the Secretary may prescribe in such regulation,

if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. No condition prescribed under subparagraph (B) may restrict the use of a device to persons with specific training or experience in its use or to persons for use in certain facilities unless the Secretary determines that such a restriction is required for the safe and effective use of the device. No such condition may exclude a person from using a device solely because the person does not have the training or experience to make him eligible for certification by a certifying board recognized by the American Board of Medical Specialties or has not been certified by such a Board. A device subject to a regulation under this subsection is a restricted device.

(2) The label of a restricted device shall bear such appropriate statements of the restrictions required

by a regulation under paragraph (1) as the Secretary may in such regulation prescribe.

21 U.S.C. § 360j(e).

FDA determined that tobacco products are restricted devices within the meaning of § 360j(e) because, due to the "unique circumstances surrounding the use of tobacco products, the only way to provide a reasonable assurance of the safety of these products is to prevent children and adolescents from using and becoming addicted to them" and that, "without the restrictions contained in the Regulations, there cannot be a reasonable assurance of the safety and effectiveness of these products." (Defs.' Br. Opp'n Pls.' Mot. Summ. J. at 93.) FDA asserts that since tobacco products are restricted devices, it may restrict their "sale, distribution, or use," pursuant to § 360j(e). FDA further asserts that it may restrict the advertising and promotion of tobacco products, explaining that advertising and promotion constitutes an "offer of sale" and, moreover, that an "offer of sale" is part of the "sale" of a product.

Plaintiffs contend, and the court agrees, that FDA may not restrict advertising and promotion pursuant to § 360j(e). First, both as ordinarily defined²³ and as used

²³ A dictionary defines sale as:

1. The exchange of goods or services for an amount of money or its equivalent; the act of selling. 2. An instance of selling property. 3. An opportunity for selling or being sold; demand. 4. Availability for purchase; *a store where pets are for sale*. 5. A selling of property to the highest bidder; auction. 6. A special disposal of goods at lowered prices; *coats on sale this week*. 7. sales. a. Activities involved in the selling of goods or services. b. Gross receipts.

in the phrase "may . . . be restricted to sale, distribution, or use," the word "sale" does not encompass the advertising or promotion of a product. Second, as Plaintiffs note, although Congress expressly used the words "offer for sale"²⁴ and "advertising" or "advertisements"²⁵ elsewhere in the FDCA, it chose not to use such language in § 360j(e).

Even if "sale," as used within § 360j(e), could be construed to encompass the advertising and promotion of a product, the court finds that the section's grant of authority to FDA to impose "other conditions" on the sale, distribution, or use of restricted devices does not authorize FDA to restrict advertising and promotion. The phrase "other conditions" must be construed within the context of § 360j(e) and other relevant sections of the FDCA. Section 360j(e) authorizes FDA to restrict the sale, distribution, or use of certain devices to prescription sale or other conditions necessary to provide a reasonable assurance of safety and effectiveness. The restriction on the advertising and promotion of a product does not fit within this framework. Furthermore, § 360j(e) must be construed in relation to 21 U.S.C. § 353(b),²⁶ which Plaintiffs assert is the counter-

The American Heritage Dictionary 1085 (2d ed.1991). The only part of the definition that could encompass promotion and advertising is part 7, which defines "sales." Section 360j(e) does not authorize FDA to restrict general "sales" activities.

²⁴ See 21 U.S.C. §§ 331(m), 331(o), and 353(c).

²⁵ See 21 U.S.C. §§ 321(n), 331(l), 331(n), 352(n), 352(q), and 352(r).

²⁶ Section 353(b) provides:

(1) A drug intended for use by man which—

part to § 360j(e) and which authorizes FDA to constrain certain drugs to prescription status. Section 353(b), like § 360j(e), authorizes FDA to restrict drugs to prescription sale. It is true, as FDA notes, that FDA's authority is broader under § 360j(e) than under § 353(b) because FDA may impose pursuant to the former "other conditions" on the sale, distribution, or use of a restricted device. Nonetheless, the meaning of "other conditions" cannot be considered without context, and the court finds that "other conditions" cannot be so broadly construed as to encompass conditions on advertising and promotion.²⁷

(A) is a habit-forming drug to which section 352(d) of this title applies; or

(B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(C) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such a drug,

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

²⁷ The court also notes that the legislative history of the restricted device provision, which was enacted as part of the MDA in 1976, suggests that Congress did not intend to give to FDA the

In addition, the court finds that Congress' delegation to FDA of limited authority to restrict the advertising of devices elsewhere in the FDCA suggests that § 360j(e) should not be construed so as to allow FDA to restrict advertising and promotion. The court notes that just as Congress gave FDA authority to limit drugs to prescription status in § 353(b), but gave FDA authority to regulate prescription drug advertisements

authority to impose unlimited conditions on the sale of restricted devices. The House Report provides, in relevant part, as follows:

Restricted Devices.—Because of the sophistication and potentially hazardous nature of some medical devices, the proposed legislation authorizes the Secretary to require that the sale or distribution of a device be restricted if he determines that, because of its potentiality for harmful effect or the collateral measures necessary to its use, there cannot otherwise be reasonable assurance of its safety and effectiveness. Under this provision . . . , such a device may be restricted to the extent that it may be sold or distributed only upon the oral or written authorization of a practitioner licensed by law to administer or use the device, or upon such other conditions as the Secretary may prescribe, except that no condition limiting the use of a device to categories of physicians defined by their training or experience may be imposed.

This provision supersedes and adds to existing authority utilized by [FDA] to require that certain devices by [sic] dispensed only upon prescription. . . .

In addition to authorizing the Secretary to limit a device to prescription status, conditions on sale or distribution could include use only within hospitals or clinics. Also, there are categories of health professionals other than physicians that have unique skills appropriate to the use of medical devices such that certain devices which would not be appropriate for use by the ordinary layman could be authorized for use by trained nurses and technicians.

H.R. 94-853 at 24-25 (1976).

in § 352(n), Congress gave FDA authority to limit certain devices to prescription status in § 360j(e), but gave FDA authority to regulate the advertising of such devices in §§ 353(q)²⁸ and 352(r).²⁹ Indeed, the fact that Congress has specifically granted to FDA the authority to regulate advertising of restricted devices in a separate section supports the court's finding that Congress did not intend to grant FDA such authority under § 360j(e).³⁰

²⁸ 21 U.S.C. § 352(q) provides, in relevant part:

A drug or device shall be deemed to be misbranded—

....

(q) Restricted devices using false or misleading advertising or used in violation of regulations.

In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360j(e) of this title.

²⁹ Section 352(r) requires that advertisements for any restricted device include certain information: the established name of the device; a brief statement of the intended uses of the device and relevant warnings; and, if determined necessary after a hearing, a description of the device's components. Section 352(r) further provides that "no advertisement of a restricted device . . . shall, with respect to the matters specified in this paragraph or covered by regulations issued hereunder, be subject to" the Federal Trade Commission Act. Plaintiffs contend, and the court agrees, that § 352(r) reveals Congress' intention that the Federal Trade Commission have primary jurisdiction over advertising.

³⁰ The court finds that § 352(q) does not provide independent authority for advertising restrictions, but rather was intended to enable FDA to take action against an advertised product that violated the restrictions validly imposed pursuant to § 360j(e).

Thus, the court finds that § 360j(e) does not grant to FDA the authority to impose restrictions on the advertisement and promotion of tobacco products. The court will, therefore, strike those regulations restricting the advertisement and promotion of tobacco products.³¹

- b. Section 360j(e) Authorizes the Food and Drug Administration to Impose Restrictions on Access to Tobacco Products.

The court finds that § 360j(e) can be construed to authorize the access restrictions imposed by FDA. First, the access restrictions imposed by FDA, unlike its advertising and promotion restrictions, directly restrict the sale or distribution of tobacco products within the meaning of § 360j(e). Second, the court finds that such conditions on the sale or distribution of tobacco products fit within what Congress intended for FDA to impose pursuant to its authority to impose "other conditions." Thus, FDA's access restrictions will stand.³²

³¹ The court does not find, as Plaintiffs urge, that FDA's unlawful imposition of advertising and promotion restrictions pursuant to § 360j(e) evidences that FDA lacks jurisdiction to regulate tobacco products under the FDCA. The court has found that tobacco products fall within the definitions of the FDCA and that FDA may regulate tobacco products pursuant to its device authorities.

³² Plaintiff National Association of Convenience Stores asserts that the Regulations' ban on self-service displays implicates the First Amendment. The court finds that the requirement that tobacco products be stored behind a counter and sold in a face-to-face exchange between a retailer and a consumer does not implicate the First Amendment. Retailers may still exhibit store

- c. Section 352 Authorizes the Food and Drug Administration to Impose Labeling Restrictions on Tobacco Products.

FDA, pursuant to § 352(r), requires tobacco products to have a statement of intended use and the established name printed on the packages. The court finds that § 352(r) clearly authorizes FDA to require restricted devices to bear the product's established name and a statement of intended use.

In conclusion, although FDA has the authority under the FDCA to impose access restrictions and labeling requirements on tobacco products, FDA lacks the authority to restrict their advertising and promotion.

II. CONCLUSION

For the reasons discussed herein, Plaintiffs' Motion for Summary Judgment will be granted in part and denied in part.³³

An order in accordance with this memorandum opinion shall be filed contemporaneously herewith.

displays promoting the sale of tobacco products. They simply will be prohibited from storing tobacco products on such displays.

³³ In light of the court's finding that FDA lacks authority under the FDCA to restrict the promotion and advertising of tobacco products, the court declines to determine whether the promotion and advertising restrictions violate the First Amendment.

ORDER

For the reasons set forth in the memorandum opinion entered contemporaneously herewith,

IT IS THEREFORE ORDERED AND ADJUDGED that Plaintiffs' Motion for Summary Judgment is granted as to the Regulations' restrictions on the promotion and advertising of tobacco products.

IT IS FURTHER ORDERED AND ADJUDGED that Plaintiffs' Motion for Summary Judgment is denied as to the Regulations' access restrictions and labeling requirements.

This order involves controlling questions of law as to which there is substantial ground for difference of opinion. Furthermore, an immediate appeal from this order may materially advance the ultimate termination of the litigation. Therefore, the court certifies this order for an interlocutory appeal pursuant to 28 U.S.C. § 1292(b).

IT IS FURTHER ORDERED that the Regulations heretofore implemented prohibiting the sale of tobacco products to minors shall remain in full force and effect pending appeal by Plaintiffs.

IT IS FURTHER ORDERED that the Food and Drug Administration shall not implement any of the additional Regulations set for implementation on August 28, 1997, pending further orders by the court.

IT IS FURTHER ORDERED that nothing set forth in this order concerning the time of implementation of the

Regulations shall prohibit either side from presenting motions to the court for a reconsideration as to the implementation of the Regulations pending appeal.

IT IS FURTHER ORDERED that absent a timely appeal or absent permission of the Court of Appeals for the Fourth Circuit to proceed with an interlocutory appeal, this matter shall proceed for ultimate disposition by the court.

APPENDIX C

IN THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

—
No. 97-1604

BROWN & WILLIAMSON TOBACCO CORPORATION;
LORILLARD TOBACCO COMPANY; PHILIP MORRIS,
INCORPORATED; RJ REYNOLDS TOBACCO COMPANY,
PLAINTIFFS-APPELLANTS

AND

COYNE BEAHM, INCORPORATED;
LIGGETT GROUP, INCORPORATED, PLAINTIFFS

v.

FOOD & DRUG ADMINISTRATION;
DAVID A. KESSLER, M.D., COMMISSIONER OF FOOD AND
DRUGS, DEFENDANTS-APPELLEES

ATTORNEYS GENERAL OF THE STATE OF MINNESOTA;
STATE OF ALASKA; STATE OF ARIZONA;
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 STATE OF OKLAHOMA; STATE OF OREGON;
 STATE OF PENNSYLVANIA; STATE OF RHODE ISLAND;
 STATE OF SOUTH DAKOTA; STATE OF TEXAS;
 STATE OF UTAH; STATE OF VERMONT;
 STATE OF WASHINGTON; STATE OF WEST VIRGINIA;
 STATE OF WISCONSIN; THE CITY AND COUNTY OF
 SAN FRANCISCO; PUBLIC CITIZEN; THE AMERICAN
 ACADEMY OF PEDIATRICS; AMERICAN CANCER
 SOCIETY; AMERICAN COLLEGE OF PREVENTIVE
 MEDICINE; AMERICAN HEART ASSOCIATION;
 AMERICAN LUNG ASSOCIATION; AMERICAN MEDICAL
 ASSOCIATION; AMERICAN MEDICAL WOMEN'S
 ASSOCIATION; AMERICAN PUBLIC HEALTH
 ASSOCIATION; AMERICAN SOCIETY OF ADDICTION
 MEDICINE; THE HMO GROUP; NATIONAL ASSOCIATION
 OF ELEMENTARY SCHOOL PRINCIPALS; NATIONAL
 ASSOCIATION OF SECONDARY SCHOOL PRINCIPALS;
 NATIONAL CENTER FOR TOBACCO-FREE KIDS; STATE
 OF KENTUCKY; WASHINGTON LEGAL FOUNDATION
 ("WLF"); MARIO ANDRETTI; DON GARLITS; AL UNSER;
 RUSTY WALLACE; CALE YARBOROUGH; RICHARD
 BURR, CASS BALLENGER, HOWARD COBLE, UNITED
 STATES REPRESENTATIVES, LAUCH FAIRCLOTH,
 UNITED STATES SENATOR, AMICI CURIAE

No. 97-1581

COYNE BEAHM, INCORPORATED; BROWN &
 WILLIAMSON TOBACCO CORPORATION; PHILIP MORRIS,
 INCORPORATED; RJ REYNOLDS TOBACCO COMPANY;
 NATIONAL ASSOCIATION OF CONVENIENCE STORES;

ACME RETAIL, INCORPORATED; UNITED STATES
 TOBACCO COMPANY; CONWOOD COMPANY, LP;
 NATIONAL TOBACCO COMPANY, LP; PINKERTON
 TOBACCO COMPANY; SWISHER INTERNATIONAL,
 INCORPORATED; CENTRAL CAROLINA GROCERS,
 INCORPORATED; J.T. DAVENPORT, INCORPORATED;
 NORTH CAROLINA TOBACCO DISTRIBUTORS
 COMMITTEE, INCORPORATED; THE AMERICAN
 ADVERTISING FEDERATION; AMERICAN ASSOCIATION
 OF ADVERTISING AGENCIES; ASSOCIATION OF
 NATIONAL ADVERTISERS, INCORPORATED;
 MAGAZINE PUBLISHERS OF AMERICA; THE OUTDOOR
 ADVERTISING ASSOCIATION OF AMERICA,
 INCORPORATED; POINT OF PURCHASE ADVERTISING
 INSTITUTE; LORILLARD TOBACCO COMPANY,
 PLAINTIFFS-APPELLEES

AND

LIGGETT GROUP, INCORPORATED, PLAINTIFF

v.

FOOD & DRUG ADMINISTRATION; DAVID A.
 KESSLER, M.D., COMMISSIONER OF FOOD AND
 DRUGS, DEFENDANTS-APPELLANTS

ATTORNEYS GENERAL OF THE STATE OF MINNESOTA;
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 STATE OF WISCONSIN; CITY AND COUNTY OF
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 MEDICINE; AMERICAN HEART ASSOCIATION;
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 ASSOCIATION; AMERICAN MEDICAL WOMEN'S
 ASSOCIATION; AMERICAN PUBLIC HEALTH
 ASSOCIATION; AMERICAN SOCIETY OF ADDICTION
 MEDICINE; THE HMOGROUP; NATIONAL ASSOCIATION
 OF ELEMENTARY SCHOOL PRINCIPALS; NATIONAL
 ASSOCIATION OF SECONDARY SCHOOL PRINCIPALS;
 NATIONAL CENTER FOR TOBACCO-FREE KIDS;
 STATE OF KENTUCKY; WASHINGTON LEGAL
 FOUNDATION ("WLF"); MARIO ANDRETTI;
 DON GARLITS; AL UNSER; RUSTY WALLACE;
 CALE YARBOROUGH; RICHARD BURR,
 CASS BALLENGER, HOWARD COBLE, UNITED STATES
 REPRESENTATIVES, LAUCH FAIRCLOTH, UNITED
 STATES SENATOR, AMICI CURIAE

No. 97-1606

COYNE BEAHM, INCORPORATED; BROWN &
 WILLIAMSON TOBACCO CORPORATION; LORILLARD
 TOBACCO COMPANY; PHILIP MORRIS,
 INCORPORATED; RJ REYNOLDS TOBACCO COMPANY;
 UNITED STATES TOBACCO COMPANY;
 CONWOOD COMPANY, LP; NATIONAL TOBACCO
 COMPANY, LP; PINKERTON TOBACCO COMPANY;

SWISHER INTERNATIONAL, INCORPORATED; CENTRAL
 CAROLINA GROCERS, INCORPORATED;
 J.T. DAVENPORT, INCORPORATED; NORTH CAROLINA
 TOBACCO DISTRIBUTORS COMMITTEE, INCORPORATED;
 THE AMERICAN ADVERTISING FEDERATION;
 AMERICAN ASSOCIATION OF ADVERTISING AGENCIES;
 ASSOCIATION OF NATIONAL ADVERTISERS,
 INCORPORATED; MAGAZINE PUBLISHERS OF AMERICA;
 THE OUTDOOR ADVERTISING ASSOCIATION OF
 AMERICA, INCORPORATED; POINT OF PURCHASE
 ADVERTISING INSTITUTE; NATIONAL ASSOCIATION OF
 CONVENIENCE STORES; ACME RETAIL,
 INCORPORATED, PLAINTIFFS-APPELLEES

AND

LIGGETT GROUP, INCORPORATED, PLAINTIFF

v.

FOOD & DRUG ADMINISTRATION; DAVID A.
 KESSLER, M.D., COMMISSIONER OF FOOD AND
 DRUGS, DEFENDANTS-APPELLANTS.
 ATTORNEYS GENERAL OF THE STATE OF MINNESOTA;
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 STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY;
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 STATE OF NORTH DAKOTA; STATE OF OHIO;
 STATE OF OKLAHOMA; STATE OF OREGON;
 STATE OF PENNSYLVANIA; STATE OF RHODE ISLAND;
 STATE OF SOUTH DAKOTA; STATE OF TEXAS;

STATE OF UTAH; STATE OF VERMONT;
 STATE OF WASHINGTON; STATE OF WEST VIRGINIA;
 STATE OF WISCONSIN; CITY AND COUNTY
 OF SAN FRANCISCO; PUBLIC CITIZEN; THE AMERICAN
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 SOCIETY; AMERICAN COLLEGE OF PREVENTIVE
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 ASSOCIATION; AMERICAN MEDICAL WOMEN'S
 ASSOCIATION; AMERICAN PUBLIC HEALTH
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 MEDICINE; THE HMO GROUP; NATIONAL ASSOCIATION
 OF ELEMENTARY SCHOOL PRINCIPALS; NATIONAL
 ASSOCIATION OF SECONDARY SCHOOL PRINCIPALS;
 NATIONAL CENTER FOR TOBACCO-FREE KIDS;
 STATE OF KENTUCKY; WASHINGTON LEGAL
 FOUNDATION ("WLF"); MARIO ANDRETTI;
 DON GARLITS; AL UNSER; RUSTY WALLACE;
 CALE YARBOROUGH; RICHARD BURR,
 CASS BALLENGER, HOWARD COBLE, UNITED
 STATES REPRESENTATIVES, LAUCH FAIRCLOTH,
 UNITED STATES SENATOR, AMICI CURIAE

No. 97-1614

NATIONAL ASSOCIATION OF CONVENIENCE STORES;
 ACME RETAIL, INCORPORATED,
 PLAINTIFFS-APPELLANTS

v.

DAVID A. KESSLER, COMMISSIONER OF THE
 FOOD & DRUG ADMINISTRATION; FOOD & DRUG
 ADMINISTRATION, DEFENDANTS-APPELLEES

ATTORNEYS GENERAL OF THE STATE OF MINNESOTA;
 STATE OF ALASKA; STATE OF ARIZONA;

STATE OF ARKANSAS; STATE OF COLORADO;
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 STATE OF NEW MEXICO; STATE OF NEW YORK;
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 STATE OF RHODE ISLAND; STATE OF SOUTH DAKOTA;
 STATE OF TEXAS; STATE OF UTAH;
 STATE OF VERMONT; STATE OF WASHINGTON;
 STATE OF WISCONSIN; STATE OF WEST VIRGINIA;
 CITY AND COUNTY OF SAN FRANCISCO; PUBLIC
 CITIZEN; THE AMERICAN ACADEMY OF PEDIATRICS;
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 PREVENTIVE MEDICINE; AMERICAN CANCER SOCIETY;
 AMERICAN LUNG ASSOCIATION; AMERICAN
 MEDICAL ASSOCIATION; AMERICAN MEDICAL
 WOMEN'S ASSOCIATION; AMERICAN PUBLIC HEALTH
 ASSOCIATION; AMERICAN SOCIETY OF ADDICTION
 MEDICINE; THE HMO GROUP; NATIONAL ASSOCIATION
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 DON GARLITS; AL UNSER; RUSTY WALLACE;
 CALE YARBOROUGH; RICHARD BURR, CASS
 BALLENGER, HOWARD COBLE, UNITED STATES
 REPRESENTATIVES, LAUCH FAIRCLOTH, UNITED
 STATES SENATOR, AMICI CURIAE

No. 97-1605

UNITED STATES TOBACCO COMPANY; BROWN &
WILLIAMSON TOBACCO CORPORATION;
CONWOOD COMPANY, LP; NATIONAL TOBACCO
COMPANY, LP; PINKERTON TOBACCO COMPANY;
SWISHER INTERNATIONAL, INCORPORATED;
CENTRAL CAROLINA GROCERS, INCORPORATED;
J.T. DAVENPORT, INCORPORATED; NORTH
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STATE OF NORTH DAKOTA; STATE OF OHIO;
STATE OF OKLAHOMA; STATE OF OREGON;
STATE OF PENNSYLVANIA; STATE OF RHODE ISLAND;
STATE OF SOUTH DAKOTA; STATE OF TEXAS;
STATE OF UTAH; STATE OF VERMONT;
STATE OF WASHINGTON; STATE OF WISCONSIN;
STATE OF WEST VIRGINIA; CITY AND COUNTY

OF SAN FRANCISCO; PUBLIC CITIZEN; THE AMERICAN
ACADEMY OF PEDIATRICS; AMERICAN CANCER
SOCIETY; AMERICAN COLLEGE OF PREVENTIVE
MEDICINE; AMERICAN HEART ASSOCIATION;
AMERICAN LUNG ASSOCIATION; AMERICAN MEDICAL
ASSOCIATION; AMERICAN MEDICAL WOMEN'S
ASSOCIATION; AMERICAN PUBLIC HEALTH
ASSOCIATION; AMERICAN SOCIETY OF ADDICTION
MEDICINE; THE HMO GROUP; NATIONAL
ASSOCIATION OF ELEMENTARY SCHOOL PRINCIPALS;
NATIONAL ASSOCIATION OF SECONDARY SCHOOL
PRINCIPALS; NATIONAL CENTER FOR TOBACCO-FREE
KIDS; STATE OF KENTUCKY; WASHINGTON LEGAL
FOUNDATION, ("WLF"); MARIO ANDRETTI,
DON GARLITS; AL UNSER; RUSTY WALLACE;
CALE YARBOROUGH; RICHARD BURR,
CASS BALLENGER, HOWARD COBLE, UNITED STATES
REPRESENTATIVES, LAUCH FAIRCLOTH,
UNITED STATES SENATOR, AMICI CURIAE

[Filed: November 10, 1998]

ORDER

On a poll of the court on the petition for rehearing en banc there voted in favor of rehearing en banc Judges Murnaghan, M. Blane Michael and Motz, and there voted against rehearing en banc Judges Widener, Ervin, Niemeyer, Luttig, Williams and Traxler.

It is accordingly ADJUDGED and ORDERED that the petition for rehearing en banc shall be, and it hereby is, denied.

The panel considered the petition for rehearing and is of opinion it is without merit.

It is accordingly ADJUDGED and ORDERED that the petition for rehearing shall be, and it hereby is, denied.

With the concurrence of Judge James H. Michael.

Judge Hall dissents. He would grant the petition for rehearing for the reasons expressed in his separate opinion filed with the opinion of the panel.

/s/ H. E. WIDENER, JR.
H.E. WIDENER, JR.
For the Court

Chief Judge WILKINSON, and Judges WILKINS, HAMILTON and KING, being disqualified, did not participate in this decision.

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APPENDIX D

21 U.S.C. 321(g)(1) provides as follows:

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

21 U.S.C. 321(h) provides as follows:

(h) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in

vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

- (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
- (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- (3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

21 U.S.C. 353(g) provides as follows:

- (1) The Secretary shall designate a component of the Food and Drug Administration to regulate products that constitute a combination of a drug, device, or biological product. The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

(A) a drug (other than a biological product), the persons charged with premarket review of drugs shall have primary jurisdiction,

(B) a device, the persons charged with premarket review of devices shall have primary jurisdiction, or

(C) a biological product, the persons charged with premarket review of biological products shall have primary jurisdiction.

21 U.S.C. 360c(a)(2) provides as follows:

(2) For purposes of this section and sections 360d and 360e of this title, the safety and effectiveness of a device are to be determined—

(A) with respect to the persons for whose use the device is represented or intended,

(B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and

(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

21 U.S.C. 360f(a) provides as follows:

(a) General rule

Whenever the Secretary finds, on the basis of all available data and information that—

(1) a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury; and

(2) in the case of substantial deception or an unreasonable and substantial risk of illness or injury which the Secretary determined could be corrected or eliminated by labeling or change in labeling and with respect to which the Secretary provided written notice to the manufacturer specifying the deception or risk of illness or injury, the labeling or change in labeling to correct the deception or eliminate or reduce such risk, and the period within which such labeling or change in labeling was to be done, such labeling or change in labeling was not done within such period;

he may initiate a proceeding to promulgate a regulation to make such device a banned device.

21 U.S.C. 360j(e) provides as follows:

(3) Restricted devices

(1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use—

(A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or

(B) upon such other conditions as the Secretary may prescribe in such regulation,

if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. No condition prescribed under subparagraph (B) may restrict the use of a device to persons with specific training or experience in its use or to persons for use in certain facilities unless the Secretary determines that such a restriction is required for the safe and effective use of the device. No such condition may exclude a person from using a device solely because the person does not have the training or experience to make him eligible for certification by a certifying board recognized by the American Board of Medical Specialties or has not been certified by such a Board. A device subject to a regulation under this subsection is a restricted device.

(2) The label of a restricted device shall bear such appropriate statements of the restrictions required by a regulation under paragraph (1) as the Secretary may in such regulation prescribe.

21 C.F.R. Part 897 provides as follows:

Subpart A—General Provisions

§ 897.1 Scope.

(a) This part sets out the restrictions under the Federal Food, Drug, and Cosmetic Act (the act) on the sale, distribution, and use of cigarettes and smokeless tobacco that contain nicotine.

(b) The failure to comply with any applicable provision in this part in the sale, distribution, and use of cigarettes and smokeless tobacco renders the product misbranded under the act.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

§ 897.2 Purpose.

The purpose of this part is to establish restrictions on the sale, distribution, and use of cigarettes and smokeless tobacco in order to reduce the number of children and adolescents who use these products, and to reduce the life-threatening consequences associated with tobacco use.

§ 897.3 Definitions.

(a) *Cigarette* means any product which contains nicotine, is intended to be burned under ordinary conditions of use, and consists of:

(1) Any roll of tobacco wrapped in paper or in any substance not containing tobacco; or

(2) Any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (a)(1) of this section.

(b) *Cigarette tobacco* means any product that consists of loose tobacco that contains or delivers nicotine and is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements pertaining to cigarettes shall also apply to cigarette tobacco.

(c) *Distributor* means any person who furthers the distribution of cigarettes or smokeless tobacco, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.

(d) *Manufacturer* means any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette or smokeless tobacco product.

(e) *Nicotine* means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl)pyridine or $C_{10}H_{14}N_2$, including any salt or complex of nicotine.

(f) *Package* means a pack, box, carton, or container of any kind in which cigarettes or smokeless tobacco are

offered for sale, sold, or otherwise distributed to consumers.

(g) *Point of sale* means any location at which a consumer can purchase or otherwise obtain cigarettes or smokeless tobacco for personal consumption.

(h) *Retailer* means any person who sells cigarettes or smokeless tobacco to individuals for personal consumption, or who operates a facility where vending machines or self-service displays are permitted under this part.

(i) *Smokeless tobacco* means any product that consists of cut, ground, powdered, or leaf tobacco that contains nicotine and that is intended to be placed in the oral cavity.

Subpart B—Prohibition of Sale and Distribution to Persons Younger Than 18 Years of Age

§ 897.10 General responsibilities of manufacturers, distributors, and retailers.

Each manufacturer, distributor, and retailer is responsible for ensuring that the cigarettes or smokeless tobacco it manufactures, labels, advertises, packages, distributes, sells, or otherwise holds for sale comply with all applicable requirements under this part.

§ 897.12 Additional responsibilities of manufacturers.

In addition to the other responsibilities under this part, each manufacturer shall remove from each point of sale all self-service displays, advertising, labeling,

and other items that the manufacturer owns that do not comply with the requirements under this part.

§ 897.14 Additional responsibilities of retailers.

In addition to the other requirements under this part, each retailer is responsible for ensuring that all sales of cigarettes or smokeless tobacco to any person comply with the following requirements:

(a) No retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age;

(b)(1) Except as otherwise provided in § 897.16(c)(2)(i) and in paragraph (b)(2) of this section, each retailer shall verify by means of photographic identification containing the bearer's date of birth that no person purchasing the product is younger than 18 years of age;

(2) No such verification is required for any person over the age of 26;

(c) Except as otherwise provided in § 897.16(c)(2)(ii), a retailer may sell cigarettes or smokeless tobacco only in a direct, face-to-face exchange without the assistance of any electronic or mechanical device (such as a vending machine);

(d) No retailer may break or otherwise open any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or a number of unpackaged cigarettes that is smaller than the quantity in the minimum cigarette package size defined in § 897.16(b), or any quantity of cigarette tobacco or smokeless

tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use; and

(e) Each retailer shall ensure that all self-service displays, advertising, labeling, and other items, that are located in the retailer's establishment and that do not comply with the requirements of this part, are removed or are brought into compliance with the requirements under this part.

§ 897.16 Conditions of manufacture, sale, and distribution.

(a) *Restriction on product names.* A manufacturer shall not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product, except for a tobacco product whose trade or brand name was on both a tobacco product and a nontobacco product that were sold in the United States on January 1, 1995.

(b) *Minimum cigarette package size.* Except as otherwise provided under this section, no manufacturer, distributor, or retailer may sell or cause to be sold, or distribute or cause to be distributed, any cigarette package that contains fewer than 20 cigarettes.

(c) *Vending machines, self-service displays, mail-order sales, and other "impersonal" modes of sale.* (1) Except as otherwise provided under this section, a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer. Examples of methods of sale that

are not permitted include vending machines and self-service displays.

(2) Exceptions. The following methods of sale are permitted:

(i) Mail-order sales, excluding mail-order redemption of coupons and distribution of free samples through the mail; and

(ii) Vending machines (including vending machines that sell packaged, single cigarettes) and self-service displays that are located in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time.

(d) *Free samples.* No manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes or smokeless tobacco.

(e) *Restrictions on labels, labeling, and advertising.* No manufacturer, distributor, or retailer may sell or distribute, or cause to be sold or distributed, cigarettes or smokeless tobacco with labels, labeling, or advertising not in compliance with subparts C and D of this part, and other applicable requirements.

Subpart C—Labels

§ 897.24 Established names for cigarettes and smokeless tobacco.

Each cigarette or smokeless tobacco package shall bear, as provided in section 502 of the act, the following established name: "Cigarettes", "Cigarette Tobacco", "Loose Leaf Chewing Tobacco", "Plug Chewing Tobacco", "Twist Chewing Tobacco", "Moist Snuff", or "Dry Snuff", whichever name is appropriate.

§ 897.25 Statement of intended use and age restriction.

Each cigarette or smokeless tobacco package, that is offered for sale, sold, or otherwise distributed shall bear the following statement: "Nicotine-Delivery Device for Persons 18 or Older".

Subpart D—Labeling and Advertising

§ 897.30 Scope of permissible forms of labeling and advertising.

(a)(1) A manufacturer, distributor, or retailer may, in accordance with this subpart D, disseminate or cause to be disseminated advertising or labeling which bears a cigarette or smokeless tobacco brand name (alone or in conjunction with any other word) or any other indicia of tobacco product identification, in newspapers; in magazines; in periodicals or other publications (whether periodic or limited distribution); on billboards, posters, and placards; in nonpoint-of-sale promotional material (including direct mail); in point-of-sale promotional

material; and in audio or video formats delivered at a point-of-sale.

(2) A manufacturer, distributor, or retailer intending to disseminate, or to cause to be disseminated, advertising or labeling for cigarettes or smokeless tobacco in a medium that is not listed in paragraph (a)(1) of this section, shall notify the agency 30 days prior to the use of such medium. The notice shall describe the medium and discuss the extent to which the advertising or labeling may be seen by persons younger than 18 years of age. The manufacturer, distributor, or retailer shall send this notice to the Division of Drug Marketing, Advertising, and Communications, 5600 Fishers Lane (HFD-40), rm. 17B-20, Rockville, MD 20857.

(b) No outdoor advertising for cigarettes or smokeless tobacco, including billboards, posters, or placards, may be placed within 1,000 feet of the perimeter of any public playground or playground area in a public park (e.g., a public park with equipment such as swings and seesaws, baseball diamonds, or basketball courts), elementary school, or secondary school.

(c) This subpart D does not apply to cigarette or smokeless tobacco package labels.

§ 897.32 Format and content requirements for labeling and advertising.

(a) Except as provided in paragraph (b) of this section, each manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated, any labeling or

advertising for cigarettes or smokeless tobacco shall use only black text on a white background. This section does not apply to advertising:

(1) In any facility where vending machines and self-service displays are permitted under this part, provided that the advertising is not visible from outside the facility and that it is affixed to a wall or fixture in the facility; or

(2) Appearing in any publication (whether periodic or limited distribution) that the manufacturer, distributor, or retailer demonstrates is an adult publication. For the purposes of this section, an adult publication is a newspaper, magazine, periodical, or other publication:

(i) Whose readers younger than 18 years of age constitute 15 percent or less of the total readership as measured by competent and reliable survey evidence; and

(ii) That is read by fewer than 2 million persons younger than 18 years of age as measured by competent and reliable survey evidence.

(b) Labeling and advertising in an audio or video format shall be limited as follows:

(1) Audio format shall be limited to words only with no music or sound effects.

(2) Video formats shall be limited to static black text only on a white background. Any audio with the video shall be limited to words only with no music or sound effects.

(c) Each manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated, advertising permitted under this subpart D, shall include, as provided in section 502 of the act, the product's established name and a statement of its intended use as follows: "Cigarettes—A Nicotine-Delivery Device for Persons 18 or Older", "Cigarette Tobacco—A Nicotine-Delivery Device for Persons 18 or Older", or "Loose Leaf Chewing Tobacco", "Plug Chewing Tobacco", "Twist Chewing Tobacco", "Moist Snuff" or "Dry Snuff", whichever is appropriate for the product, followed by the words "A Nicotine-Delivery Device for Persons 18 or Older".

§ 897.34 Sale and distribution of nontobacco items and services, gifts, and sponsorship of events.

(a) No manufacturer and no distributor of imported cigarettes or smokeless tobacco may market, license, distribute, sell, or cause to be marketed, licensed, distributed, or sold any item (other than cigarettes or smokeless tobacco) or service, which bears the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

(b) No manufacturer, distributor, or retailer may offer or cause to be offered any gift or item (other than cigarettes or smokeless tobacco) to any person purchasing cigarettes or smokeless tobacco in consideration of the purchase thereof, or to any person in

consideration of furnishing evidence, such as credits, proofs-of-purchase, or coupons, of such a purchase.

(c) No manufacturer, distributor, or retailer may sponsor or cause to be sponsored any athletic, musical, artistic, or other social or cultural event, or any entry or team in any event, in the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco. Nothing in this paragraph prevents a manufacturer, distributor, or retailer from sponsoring or causing to be sponsored any athletic, musical, artistic, or other social or cultural event, or team or entry, in the name of the corporation which manufactures the tobacco product, provided that both the corporate name and the corporation were registered and in use in the United States prior to January 1, 1995, and that the corporate name does not include any brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

MAR 22 1999

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No. 98-1152

IN THE
Supreme Court of the United States
OCTOBER TERM, 1998

FOOD AND DRUG ADMINISTRATION, *et al.*,
Petitioners,

v.

BROWN AND WILLIAMSON TOBACCO CORP., *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the
United States Court of Appeals
for the Fourth Circuit

**RESPONDENTS' BRIEF IN OPPOSITION TO
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QUESTION PRESENTED

Whether the Food and Drug Administration has jurisdiction to regulate the continued marketing of tobacco products, despite the facts that (1) its governing statute requires it to ban "unsafe" products, and (2) Congress has enacted a series of tobacco-specific statutes, which are premised on the continued marketing of tobacco products and which provide no role for FDA? *

* FDA's assertion of jurisdiction relates to cigarettes and smokeless tobacco products. See 21 C.F.R. § 897.1(a) (1998). All references herein to "tobacco products" are to cigarettes and smokeless tobacco products "as customarily marketed." The words "as customarily marketed" are FDA's. Letter from Mark Novitch for FDA Comm'r Jere Goyan 12 (Nov. 22, 1980) (FDA Dkt. Nos. 77P-0185, 78P-0338/CP). Those words refer to the marketing of cigarettes and smokeless tobacco products with the customary claims (*e.g.*, "smoking satisfaction," "good taste"), in contrast to claims of a health benefit.

RULE 29.6 LISTING

Pursuant to Supreme Court Rule 29.6, Respondents submit the following corporate information:

1. Acme Retail, Inc., has no parent companies and has no nonwholly owned subsidiaries.

2. The parent companies of Brown & Williamson Tobacco Corporation are:

British American Tobacco p.l.c.
 British American Tobacco (1998) Limited
 BAT Industries p.l.c.
 British American Tobacco (Holdings) Limited
 Louisville Securities Limited
 BATUS Holdings Inc.
 BATIC, Inc.
 BATUS Tobacco Services, Inc.

Brown & Williamson Tobacco Corporation has no nonwholly owned subsidiaries.

3. Central Carolina Grocers, Inc., is a North Carolina corporation which is owned by one hundred ten (110) individuals and entities, none of whom individually own ten percent (10%) or more of the capital stock of the corporation. Central Carolina Grocers, Inc., has no nonwholly owned subsidiaries.

4. The parent companies of Conwood Company, L.P., are:

Asworth Corporation
 Conwood LLC
 HT Forum, Inc.
 Dalfort Aviation Services, Inc.

Conwood Company, L.P., has no nonwholly owned subsidiaries.

5. Coyne Beahm, Inc., has no parent companies and has no nonwholly owned subsidiaries.

6. J.T. Davenport, Inc., has no parent companies and has no nonwholly owned subsidiaries.

7. The parent companies of Lorillard Tobacco Company are Lorillard, Inc., and Loews Corporation. Lorillard Tobacco Company has no nonwholly owned subsidiaries.

8. National Association of Convenience Stores has no parent companies and has no nonwholly owned subsidiaries.

9. The parent company of National Tobacco Company, L.P., is North Atlantic Trading Company, Inc. National Tobacco Company, L.P., has no nonwholly owned subsidiaries.

10. North Carolina Tobacco Distributors Committee, Inc., has no parent companies and has no nonwholly owned subsidiaries.

11. The parent company of Philip Morris Incorporated is Philip Morris Companies, Inc. Philip Morris Incorporated has no nonwholly owned subsidiaries.

12. The parent companies of The Pinkerton Tobacco Company are Swedish Match AB and Swedish Match North America Inc. The Pinkerton Tobacco Company has no nonwholly owned subsidiaries.

13. R.J. Reynolds Tobacco Company is the indirect subsidiary of RJR Nabisco Holdings Corp. (R.J. Reynolds Tobacco Company is wholly owned by RJR Nabisco, Inc., which is wholly owned by RJR Nabisco Holdings Corp., which is publicly held). Nabisco Holdings Corp. is the publicly held affiliate of R.J. Reynolds Tobacco Company.

The subsidiaries of R.J. Reynolds Tobacco Company that are not wholly owned are:

AOISMA
 AO3T Kabisco

Camel Racing Inc.-Courses Camel Inc.
 China-American Cigarette Company Limited
 Modi RJR Limited
 OAO Electronmash
 R.J. Reynolds Berhad
 R.J. Reynolds-Da Nang Tobacco Company Limited
 R.J. Reynolds Espana, S.L.
 R.J. Reynolds/M.C. Tobacco Company, Limited
 R.J. Reynolds Tobacco Baku
 R.J. Reynolds Tobacco Kazakhstan
 R.J. Reynolds Tobacco-Kremenchuk
 R.J. Reynolds Tobacco Lviv ISC
 Reynolds Manufacturing (Bulgaria) Ltd.
 Reynolds Manufacturing (Romania) S.A.
 RJR-Armavirtabak, OAO
 RJR Tobacco Yelets., OAO
 Tabandor S.A.
 Tanzania Cigarette Company
 TOO RJR-Petro

On March 9, 1999, R.J. Reynolds Tobacco Company and its parent company, RJR Nabisco Holdings Corp., announced that they had entered into a definitive agreement to sell their international tobacco business to Japan Tobacco, Inc. The non-wholly owned subsidiaries of R.J. Reynolds Tobacco Company identified in this disclosure are part of the international tobacco business that is to be sold. The companies expect the sale to be completed approximately sixty (60) days after the announcement.

On March 9, 1999, RJR Nabisco Holdings Corp. also announced that its Board of Directors had approved a plan to separate R.J. Reynolds Tobacco Company from its Nabisco food business. The separation will be accomplished by a spin-off to RJR Nabisco Holdings Corp. shareholders of shares in R.J. Reynolds Tobacco Company. After the spin-off, RJR Nabisco Holdings Corp.

and RJR Nabisco, Inc., will no longer be parent companies of R.J. Reynolds Tobacco Company. The spin-off is anticipated to occur as soon as practicable after the sale of the international tobacco business.

14. The parent company of Swisher International, Inc., is Swisher International Group, Inc. Swisher International, Inc., has no nonwholly owned subsidiaries.

15. The parent company of United States Tobacco Company is UST Inc. United States Tobacco Company has no nonwholly owned subsidiaries.

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INTRODUCTION

The Government argues that failure to overturn the court of appeals' decision "will deprive the public of an unparalleled opportunity to prevent millions of children from" using tobacco. Petition for a Writ of Certiorari ("Pet.") 15-16.

To the contrary, "the public"—through its elected representatives in Congress—has already addressed the complex and highly political issues of tobacco and health, including underage access. In a series of tobacco-specific statutes in 1965, 1970, 1983, 1984, 1986, and 1992, Congress crafted a national regulatory policy premised on the continued availability of tobacco products, even though they are deemed to be unsafe. *See, e.g.*, 15 U.S.C. § 1331 (this and other relevant statutes are included in Respondents' Appendix). Congress gave FDA no role in the administration of these statutes or this policy. Far from seeking to preserve the public's opportunity to regulate tobacco, FDA simply seeks to supplant enacted policy by disregarding statutes with which it disagrees and short-circuiting an on-going political process.

There is no reason to grant the writ. The decision of the court of appeals is correct. It properly applied the relevant precedents of this Court and correctly interpreted the relevant statutes. It does not conflict with any decision of this Court or any other court.¹ Its scope is limited. It addresses only the question of FDA's jurisdiction over tobacco products. It does not affect FDA's authority with respect to the kinds of products FDA has historically regulated; nor does

¹ Indeed, it is consistent with the two closest appellate decisions, *ASH v. Harris*, 655 F.2d 236 (D.C. Cir. 1980) (upholding FDA's denial of jurisdiction over tobacco products), and *FTC v. Liggett & Myers Tobacco Co.*, 203 F.2d 955 (2d Cir. 1953), *aff'g on opinion below*, 108 F. Supp. 573 (S.D.N.Y. 1952) (interpreting language in FTC Act identical to that in Food, Drug, and Cosmetic Act as not covering tobacco products).

it affect the regulation of tobacco products under other laws.²

COUNTER-STATEMENT

The Petition neglects: (i) the critical differences between the public policy issues raised by tobacco products and those raised by the products historically regulated by FDA, (ii) Congress's enactment of statutes specifically designed to address the distinctive issues tobacco products raise, (iii) FDA's advice to Congress that the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA") does not apply to tobacco products and would ban them if it did, (iv) the extensive regulation of tobacco products under other federal and state laws, and (v) the current congressional attention to this issue.

1. For most of this century, tobacco and tobacco products have constituted a major and separate sector of the nation's economy.³ In the 1930s, when Congress was considering the FDCA, cigarettes were smoked by approximately 37% of the adult population. U.S. Dep't of Health & Human Servs., *The Health Consequences of Smoking to Women* 23 (1980). Today, they are smoked by about 23% of adults, nearly 50 million people. Centers for Disease Control and Prevention, *Morbidity & Mortality*

² The Petition refers frequently to the restrictions on advertising in FDA's tobacco rule. Yet, the Government does not seek review of the question of FDA's statutory authority to regulate tobacco product advertising. Nor could it. Although the district court held that FDA's advertising regulations were not authorized by 21 U.S.C. § 360j(e), the court of appeals was careful to vacate that judgment and state that it expressed no view on the matter. Pet. App. 54a n.29. The constitutional challenge to those regulations was not reached by the district court, *see id.* at 134a n.33, and, of course, was not addressed by the court of appeals.

³ *See, e.g.*, U.S. Dep't of Commerce, *Statistical Abstract of the United States, passim* (1938) (separate statistics for tobacco sector); Technical Committee on Industrial Classification, Executive Office of the President, 1 *Standard Industrial Classification Manual* xi, 8, 25 (1941) (separate SIC codes for tobacco products).

Weekly Report (Nov. 6, 1998). Tobacco is critical to the economies of certain States and communities. Consequently, establishing national tobacco policy has always been a political task for Congress.

2. From the beginning of this century, there has been widespread concern that tobacco adversely affects health.

Between 1895 and 1921, 14 States banned cigarettes; and all the others enacted prohibitions on their sale to minors.⁴ In *Austin v. Tennessee*, 179 U.S. 343, 348 (1900), this Court, in upholding a ban, observed that "belief in [cigarettes'] deleterious effects . . . has become very general." This Court has noted that "physicians had suspected a link between smoking and illness for centuries," and "the first medical studies of that connection" appeared in the 1920s. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 513 (1992).

Given these longstanding concerns, Congress could not have assumed that tobacco products could meet the requirement embodied in the FDCA in 1938 that drugs be affirmatively shown to be safe in order to be distributed. *See* FDCA § 505(d)(2), Pub. L. No. 75-717, § 505(d)(2), 52 Stat. 1040, 1052 (1938) (codified at 21 U.S.C. § 355(d)(2)). Moreover, tobacco products cannot be marketed as medical products under the FDCA because they do not provide any *therapeutic* benefits that FDA would view as justifying their risks.

Prohibition of alcohol ended in 1933, the year Congress began considering what was to become the FDCA. The idea that Congress in 1938 intended to give an administrative agency the power on its own to institute a new Prohibition defies common sense.

⁴ Elaine Nuehring & Gerald E. Markle, *Nicotine and Norms: The Re-Emergence of a Deviant Behavior*, 21 *Social Problems* 513, 515 (1974); 1899 Tex. Gen. Laws Ch. 139, § 1 (codified at Tex. Penal Code art. 1049 (1911)).

In 1964, the landmark first Surgeon General's Report on Smoking and Health concluded that cigarettes have serious adverse effects on the body. U.S. Dep't of HEW, *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service* (1964). The Report described some tobacco use as similar to "drug habituation," which is "reinforced and perpetuated by the pharmacological actions of nicotine on the central nervous system." *Id.* at 350, 354. The published studies cited in the report made these effects foreseeable and, therefore, under FDA's present interpretation of 21 U.S.C. §§ 321(g)(1)(C) and 321(h)(3), "intended."

In 1970, Congress required that cigarette packs and cartons state: "Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health." Pub. L. No. 91-222, § 4, 84 Stat. 87, 88 (1970). This warning further reflected the consensus among public health authorities that cigarettes have foreseeable adverse effects on the body. *See Larus & Brother v. FCC*, 447 F.2d 876 (4th Cir. 1971) (upholding FCC action based on that consensus).

3. Thus, owing to their widespread use, national and regional economic importance, perceived risks, and lack of therapeutic benefits, tobacco products have long presented public policy issues very different from those presented by foods, drugs, medical devices, and cosmetics. These circumstances help explain why neither the text of the 1938 FDCA nor its legislative history mentions tobacco products or the distinctive issues they raise.

4. FDA's contemporaneous interpretation of the FDCA, even before the enactment of any of the tobacco-specific statutes, was that the FDCA does not apply to tobacco products. In defending that interpretation, the Government pointed out:

After the passage of the 1938 Act, FDA repeatedly informed Congress that cigarettes were not comprehended by the statutory definition of the term "drug" absent health claims on behalf of the manufacturer or vendor. . . . These records . . . includ[e] correspondence dating from at least as early as 1940. . . . Brief for Gov't Appellee (FDA) 16, 22 n.19, *ASH v. Harris*, 655 F.2d 236 (D.C. Cir. 1980).

In 1963, FDA explained its interpretation:

1. The statutory basis for the exclusion of tobacco products from FDA's jurisdiction is the fact that tobacco marketed for chewing or smoking without accompanying therapeutic claims, does not meet the definitions in the [FDCA] for food, drug, device or cosmetic.
2. Congress did not consider problems that might arise from the use of tobacco when it considered the bills during the 1933-38 period, which led to the enactment of the [FDCA].

Memorandum from FDA Bureau of Enforcement to Directors of Bureaus and Divisions and Directors of Districts (May 23, 1963), *reprinted in Public Health Cigarette Amendments of 1971: Hearings on S. 1454 Before the Consumer Subcomm. of the Senate Comm. on Commerce*, 92d Cong. 240 (1972).

5. In response to the 1964 Surgeon General's Report, Congress enacted the Federal Cigarette Labeling and Advertising Act ("FCLAA"), Pub. L. No. 89-92, 79 Stat. 282 (1965), which established a separate regulatory program for tobacco, and provided no role for FDA. In developing the FCLAA, Congress focused, for the first time, on whether to authorize FDA to regulate tobacco products. At that crucial time, both the Department of Health, Education, and Welfare ("HEW") and FDA told Congress that the FDCA gave the agency no jurisdiction.

Surgeon General Luther Terry testified: "[W]e do not have such authority [*i.e.*, over the labeling or advertising

of cigarettes] in existing laws governing the Public Health Service and [FDA]." *Cigarette Labeling & Advertising Relative to Health Problems Associated with Smoking: Hearings Before the House Comm. on Interstate and Foreign Commerce*, 88th Cong. 56 (1964) ("1964 House Hearings"). FDA testified: "The [FDA] has no jurisdiction under the [FDCA] over tobacco, unless it bears drug claims." *Cigarette Labeling and Advertising—1965: Hearings Before the House Comm. on Interstate and Foreign Commerce*, 89th Cong. 193 (1965) ("1965 House Hearings") (testimony of FDA Ass't Comm'r Winton Rankin).⁵ In light of this testimony, Congress had no reason to amend the FDCA to exclude tobacco products.

Two bills proposed to give FDA jurisdiction under the FDCA. See *1964 House Hearings* 4-5 (H.R. 5973), 6-7 (H.R. 9512). HEW Secretary Anthony J. Celebrezze advised that such jurisdiction "might well" lead to a ban, a result he characterized as not intended and not acceptable to the American people. *Id.* at 18. The proposal was abandoned without controversy. See *1965 House Hearings* 29.

Instead, Congress embodied in the FCLAA a new regulatory program for tobacco, outside the FDCA and premised on the continued availability of tobacco products:

It is the policy of the Congress, and the purpose of this Act, to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby—

⁵ This testimony was also referred to in the Senate. 111 Cong. Rec. 13431 (June 16, 1965). The position that FDA's jurisdiction depends on claims was not unique to tobacco products, but, rather, reflected general food and drug law. Despite occasional contrary dicta over the decades, no court has ever held that a product is a "drug" or medical "device" in the absence of a therapeutic claim for the product. See *Pet. App.* 19a (quoting the district court, *Pet. App.* 107a).

(1) the public may be adequately informed that cigarette smoking may be hazardous to health by inclusion of a warning to that effect on each package of cigarettes; and

(2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.

FCLAA § 2, Pub. L. No. 89-92, § 2, 79 Stat. 282, 282 (codified as amended at 15 U.S.C. § 1331) (emphasis added). Congress has amended the FCLAA twice, but has retained Section 1331 essentially unchanged, and has never given FDA any role in the tobacco regulatory program.⁶

6. The FDCA does not equip FDA to administer the policy stated in Section 1331. The FDCA mandates that all marketed drugs and medical devices be therapeutically effective and safe, see *Pet. App.* 20a-29a; see also 21 U.S.C. § 393(b)(2)(B)-(C), and does not provide for "protect[ion of]" "commerce and the national economy . . . to the maximum extent consistent with [the giving of warnings]."

To protect the balance expressed in Section 1331, the FCLAA also prohibits any federal agency from requiring on cigarette packages any "statement relating to smoking and health" different from the warnings prescribed in the FCLAA, 15 U.S.C. § 1334(a). A parallel provision applies to smokeless tobacco products. See *id.*

⁶ In 1984, when amending the FCLAA's provisions on warnings, Congress reaffirmed Section 1331 by keeping it intact and, to conform paragraph (1) to the revised warnings, amending it to read: "the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes. . . ." Pub. L. No. 98-474, § 6(a), 98 Stat. 2200, 2204 (1984) (codified at 15 U.S.C. § 1331).

§ 4406(a). These provisions preclude FDA from requiring on tobacco products the kind of directions for safe use that are central to FDA's regulation of all drugs and medical devices sold over-the-counter to consumers. *See* 21 U.S.C. § 352(f)(1); 21 C.F.R. §§ 201.5, 801.5 (1998).

7. Since 1965, Congress has continually responded to evolving public concerns about tobacco and health by enacting new statutes, which have expanded its tobacco regulatory program.

In 1970, Congress amended the FCLAA by, *inter alia*, changing the warning on cigarette packages, and, to reduce underage smoking, by banning cigarette advertising on television and radio. *See* Pub. L. No. 91-222, 84 Stat. 87 (1970).

In 1983, Congress directed the Secretary of Health and Human Services ("HHS") to report to Congress every three years on research findings on "the addictive property of tobacco," and to include recommendations for legislation and administrative action. Pub. L. No. 98-24, § 505(b)(2)-(3), 97 Stat. 175, 178 (1983) (codified at 42 U.S.C. § 290aa-2(b)(2)-(3)).

In 1984, Congress again amended the FCLAA, to require four rotating warnings on cigarette packages and advertisements, disclosure of tobacco ingredients to HHS, and the establishment of an Interagency Committee on Smoking and Health, which does not include FDA. *See* Pub. L. No. 98-474, 98 Stat. 2200 (1984).

In 1986, the Comprehensive Smokeless Tobacco Health Education Act created for smokeless tobacco products a regulatory program similar to that for cigarettes under the FCLAA. *See* Pub. L. No. 99-252, 100 Stat. 30 (1986).

In 1992, Congress addressed underage access to tobacco products. The statute embodied a two-part strategy: (i) it left the initiative with the States, exercising

their traditional police power; and (ii) it provided financial incentives to the States to increase the effectiveness of their restrictions on underage access. *See* Pub. L. No. 102-321, § 202, 106 Stat. 323, 394 (1992) (codified at 42 U.S.C. § 300x-26).

8. During this entire period, FDA repeatedly reiterated its position that it had no jurisdiction over tobacco products.

In 1972, FDA testified that an assertion of jurisdiction over tobacco products would lead to a ban—a result FDA characterized as not intended by Congress:

[C]igarettes recommended for smoking pleasure are beyond the [FDCA]. . . . [I]f cigarettes were to be classified as drugs, they would have to be removed from the market because it would be impossible to prove they were safe for their intended use. . . . [The FCLAA] . . . demonstrates that the regulation of cigarettes is to be the domain of Congress. . . . In sum, labeling or banning cigarettes is a step that can be take[n] only by Congress. Any such move by FDA would be inconsistent with the clear congressional intent.

Public Health Cigarette Amendments of 1971, Hearings on S. 1454 Before the Consumer Subcomm. of the Senate Comm. on Commerce, 92d Cong. 242 (1972) (testimony of FDA Comm'r Charles Edwards). Thus, FDA recognized that: (i) ordinary tobacco products lie beyond the FDCA as a definitional matter; (ii) tobacco products, if made subject to the FDCA, could not satisfy its requirements for the marketing of medical products; and (iii) the FCLAA confirms Congress's exclusive responsibility for dealing with the health risks associated with tobacco use.

In 1977, Action on Smoking and Health ("ASH") petitioned FDA to regulate cigarettes as "drugs" or "devices" on the ground that their nicotine produces a "phy-

sical addiction" in many smokers, including those who begin smoking when young. *Citizen Petition*, FDA Dkt. No. 77P-0185, at 4-10 (May 26, 1977).

As FDA now asserts, ASH then asserted that: (1) cigarettes and nicotine are drugs, *id.* at 2; (2) cigarettes affect the structure and function of the body, *id.* at 2, 7; (3) studies demonstrate that many smokers smoke for the "physiological effects the drug causes on their body," *id.* at 2; (4) numerous studies demonstrate that nicotine has effects similar to those of heroin and other addictive substances, *id.*; (5) studies since 1940 indicate that smoking is a method of "administering a carefully controlled dose of nicotine to the body," *id.* at 8; (6) a "cigarette is, after all, an instrument, apparatus, or contrivance designed to administer controlled amounts of nicotine and other substances to the smoker upon demand," *id.* at 31; and (7) children have easy access to tobacco, *id.* at 36.

FDA did not dispute *any* of ASH's factual presentations. Rather, it denied the petition on the ground that they could not be a basis for FDA jurisdiction.⁷ FDA stated that its "interpretation of the . . . [FDCA] consistently has been that cigarettes are not a drug unless health claims are made by the vendors." Letter from Comm'r Donald Kennedy to John F. Banzhaf, III, at 3 (Dec. 5, 1977) (FDA Dkt. No. 77P-0185).

When ASH sought judicial review, the Government responded:

Since at least the issuance of the Surgeon General's Report on Smoking in 1964, cigarettes have been at the forefront of discussions of the public health—in Congress, in the Executive Branch, in the news media, and among the public generally. The participants in these discussions over the past 15 years

⁷ FDA's 1977 decision rejected only ASH's claim that cigarettes are "drugs." FDA rejected ASH's claim that they are devices in denying ASH's second petition, discussed at pp. 11-12, *infra*.

or more would be shocked to learn that during this time FDA has had jurisdiction to regulate cigarettes as drugs, and presumably to ban them.

Brief for Government Appellee 40, *ASH*, 655 F.2d 236. The court of appeals agreed that, "if the [FDCA] requires expansion [to cover cigarettes], it is the job of Congress." 655 F.2d at 243.

In 1978, ASH again petitioned FDA. *Citizen Petition*, FDA Dkt. No. 78P-0338/CP (Oct. 2, 1978). It claimed that filtered cigarettes are medical "devices" under the FDCA. While that petition was pending, the National Institute on Drug Abuse ("NIDA") issued a report finding that "cigarette smoking should be considered a form of addiction, and tobacco in the form of cigarettes, an addicting substance."⁸ Indeed, as Dr. William Pollin, the Director of NIDA, later testified: "The conclusion that cigarette smoking behavior is an addictive disorder . . . became confirmed internationally back in 1979." *Smoking Prevention Health and Education Act of 1983: Hearings Before the Senate Comm. on Labor and Human Resources*, 98th Cong. 58 (1983) (emphasis added).

Nevertheless, again without rejecting any of ASH's factual presentations, FDA concluded in 1980 that cigarettes are not "devices." Having reviewed the Medical Device Amendments of 1976 and their legislative history, FDA concluded, in unusually strong terms: "It is, therefore, not reasonable to consider cigarettes as 'devices' when there was no discussion in the legislative history of congressional intent to provide jurisdiction over cigarettes or to provide authority suitable to the regulation of cigarettes." Letter from Mark Novitch for FDA Comm'r Jere Goyan 3

⁸ National Institute on Drug Abuse, Technical Review on Cigarette Smoking as an Addiction, Final Report (1979), reprinted in *Comprehensive Smoking Prevention Education Act: Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 97th Cong. 340, 346 (1982).

(Nov. 25, 1980) (FDA Dkt. Nos. 77P-0185, 78P-0338/CP). FDA also stated: "Insofar as rulemaking would relate to cigarettes . . . as customarily marketed, we have concluded that FDA has no jurisdiction under [the FDCA]. Therefore, no rulemaking is permissible as a matter of law." *Id.* at 12.⁹

In 1988, FDA explained to Congress how nicotine in therapeutic products is within FDA's jurisdiction, but nicotine in tobacco products is not:

Tobacco products, as they have been customarily marketed, have not been considered by FDA to be within any of the categories of articles over which we have jurisdiction. . . . [C]igarettes or other tobacco products can be "drugs" if the manufacturer or vendor were to make medical claims for the product. . . .

On the other hand, [a product] which does not contain tobacco but instead contains nicotine, the principal pharmacological agent found in tobacco, is regarded as a "drug" because the manufacturer clearly intended and labeled it as a smoking deterrent to satisfy a nicotine dependence.

Health Consequences of Smoking: Nicotine Addiction: Hearing Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 100th Cong. 17-19 (1988) (testimony of FDA Comm'r

⁹ The view that the FDCA does not provide authority suitable to the regulation of cigarettes was echoed as recently as 1994 by FDA Commissioner David Kessler, who testified that "[t]he tools are limited," and that an assertion of jurisdiction by FDA could have "enormous social consequences." *Regulation of Tobacco Products (Part 1): Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 103d Cong. 68-69 (1994)*. Commissioner Kessler stated that, on this issue, FDA was "seek[ing] guidance from the Congress." *Id.* at 33. Immediately after the 1994 elections changed the political control of Congress, however, FDA decided to proceed on its own. See Letter from Diane E. Thompson, FDA Assoc. Comm'r for Legislative Affairs, to Hon. Martin Lancaster 2 (Nov. 10, 1994).

Frank Young). This statement also explains why "stimulants, tranquilizers, appetite suppressants, nicotine replacement products, and narcotics used to treat addiction," Pet. 18, are within FDA's jurisdiction, but tobacco products are not.

None of FDA's statements disavowing jurisdiction relied on policy, discretion, or lack of evidence.¹⁰ Moreover, before 1995, FDA never tried to subject *any* tobacco product to ongoing regulation.¹¹ Rather, until the rulemaking now at issue, the agency's consistent view was that tobacco products are outside its jurisdiction *as a matter of law and congressional intent*.

9. The regulation of tobacco products is extensive and growing—apart from FDA. Many federal statutes address the health concerns relating to tobacco:

- Congress has addressed underage access to tobacco products by requiring HHS to condition federal funding of certain state programs on the adoption

¹⁰ FDA now seeks to explain its past disavowals as due to ignorance of "recently-discovered evidence" that tobacco companies: (i) knew that nicotine is addictive and (ii) designed their products to deliver precise amounts of nicotine. Pet. 5, 26. Even if taken at face value, however, this "evidence" is the same type of "evidence" FDA previously rejected, as a matter of law, as not a basis for jurisdiction. ASH's 1977 Petition alleged that nicotine was addictive (and the 1964 Surgeon General's Report referred to tobacco use as a "habituation" due to nicotine's "pharmacological actions") and that cigarettes are used by smokers and "designed [by manufacturers] to administer controlled amounts of nicotine," factual allegations FDA viewed as irrelevant. See pp. 4, 10, *supra*.

¹¹ In the 1950s, FDA did drive off the market two cigarette products that made therapeutic claims. See *United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (D.N.J. 1959); *United States v. 46 Cartons . . . Fairfax Cigarettes*, 113 F. Supp. 336 (D.N.J. 1953). However, the theory of those cases did not relate particularly to tobacco products, and would have applied to *any* consumer product that made such claims. See, e.g., *United States v. 23 . . . Articles, etc.*, 192 F.2d 308 (2d Cir. 1951) (phonograph records that claimed to induce sleep were medical devices).

and enforcement by each State of an 18-year-old minimum purchase age. *See* 42 U.S.C. § 300x-26.

- Congress has banned advertisements of tobacco products from any electronic medium, including television and radio, subject to the jurisdiction of the Federal Communications Commission. *See* 15 U.S.C. §§ 1335, 4402(f).
- Congress has designated the Federal Trade Commission ("FTC") to oversee compliance with statutory requirements for warning labels on all tobacco packages and in all tobacco product advertisements. *See* 15 U.S.C. §§ 1333(a)(1), 4402(a)-(d).¹²
- Congress has directed the FTC to report annually to Congress about tobacco product advertising, and to recommend legislation on that subject. *See* 15 U.S.C. §§ 1335a, 4403.
- Congress requires tobacco product manufacturers to disclose to HHS annual lists of ingredients used in tobacco products and requires HHS to review the lists and to report to Congress on any perceived health effects. *See* 15 U.S.C. §§ 1335a, 4403.¹³
- Congress has banned smoking on airplanes, *see* 49 U.S.C. § 41706, and in schools that receive federal funds, *see* 20 U.S.C. § 6083.
- Congress has directed HHS to transmit to Congress reports that describe current research findings on the asserted addictive property of tobacco and that recommend legislation or administrative action. *See* 42 U.S.C. § 290aa-2.

¹² The FTC also regulates advertising of tobacco products under the Federal Trade Commission Act. *See* 15 U.S.C. §§ 41-64.

¹³ Thus, Congress has already provided a means to address the Government's concern about a potentially hazardous ingredient in a tobacco product. Pet. 28.

- Congress has directed HHS to report annually to Congress on current information about the health consequences of using tobacco products, and to include any recommendations for legislation. *See* 15 U.S.C. §§ 1337(a), 4407(a).
- Congress has directed HHS to analyze and publish research on the reported health effects of smoking, *see* 15 U.S.C. § 1341(a); it is assisted in that effort by an Interagency Committee on Smoking and Health, *see* 15 U.S.C. § 1341(b).

Thus, the tobacco-specific statutes do not address "narrow issues," Pet. 27, or "different issues" from those addressed by FDA's regulations, *id.* at 20. They address, *inter alia*, underage access, advertising, and labeling, in the manner chosen by Congress. These are the very concerns FDA asserts as the bases for its late entry into this field.

In addition, hundreds of state and local laws restrict the sale of tobacco products to prevent access by minors. Every State prohibits the sale of tobacco products to persons under age 18. In response to varying circumstances and public preferences, the States have enacted a variety of additional provisions relating to proof of age for purchase, licensing of tobacco retailers, product displays, vending machines, and product samples.

Finally, the Government, itself, raises the fact that nearly all the States have entered into a Master Settlement Agreement ("MSA") with the principal tobacco product manufacturers. *See* Pet. 16, 29 n.9.¹⁴ That agreement establishes significant restrictions on tobacco advertising,

¹⁴ The settlement appears at <<http://www.naag.org/tob2.htm>>. It has been entered into by all 46 States that had not previously settled with the industry, and by the District of Columbia and five territories. The settling cigarette manufacturers account for over 99% of the U.S. cigarette market. United States Tobacco Company, which entered into a parallel agreement with 45 States, the District of Columbia, and five territories, accounts for approximately 55% of the U.S. smokeless tobacco category.

which are embodied in judicially enforceable consent decrees immune from constitutional or statutory challenge.

The MSA contains numerous provisions that address many of the subjects of FDA's regulations. These include: prohibitions against targeting youth and against use of cartoon characters; sweeping restrictions on outdoor tobacco advertising; a prohibition against certain brand-name sponsored events; and a ban on the distribution of non-tobacco merchandise with the brand name, logo, or trademark of a tobacco product. It also bars manufacturers from distributing free samples of tobacco products, except in adult-only facilities. See MSA § III (a)-(g).

These tobacco-control initiatives can be evaluated by Congress as it considers whether to enact new legislation to dramatically extend FDA's authority to include tobacco products.

10. Legislation relating to FDA jurisdiction over tobacco products was considered on the Senate floor and in House hearings in the 105th Congress;¹⁵ and the President, in his recent State of the Union Address, called for such legislation in the 106th Congress, see 145 Cong. Rec. H258, H260 (daily ed. Jan. 19, 1999). Thus, the question whether to grant FDA jurisdiction over tobacco products is actively before Congress.

REASONS FOR DENYING THE WRIT

1. FDA contends that it has the authority to ban tobacco products, and that the exercise of that authority

¹⁵ See, e.g., 144 Cong. Rec. S4883 (daily ed. May 14, 1998) (motion to consider tobacco bill); *id.* at S6433-85 (daily ed. June 17, 1998) (point of order against bill sustained); *The Tobacco Settlement: Views of the Administration and the State Attorneys General: Hearings Before the House Comm. on Commerce*, 105th Cong. (1997); *The Tobacco Settlement—Part 3: Hearings Before the Subcomm. on Health and Environment of the House Comm. on Commerce*, 105th Cong. (1998).

is a matter of its discretion. See 61 Fed. Reg. 44,396, 44,405, 44,412-13 (1996); 60 Fed. Reg. 41,314, 41,349, 41,523-24 (1995). Even as it was deciding whether it had jurisdiction, FDA seriously considered whether to ban tobacco products, and found the question a "close" one. 61 Fed. Reg. 44,416. For now, it has rejected a ban because a ban would "overwhelm[]" the health care system by the need to treat smokers, and a "black market and smuggling would develop. . . ." Pet. 23 (citing 61 Fed. Reg. 44,413).

These very grounds, presented to show that "[FDA's] public health policy conclusion [not to ban tobacco products] was well-founded," Pet. 23, demonstrate that FDA has overreached. Not merely "public health policy" considerations, but also law enforcement, national and regional economics, federal and state tax revenues, public preferences, and other factors, would have to be weighed in deciding whether to ban tobacco products. This multifaceted issue far transcends FDA's medical and scientific expertise; and FDA has no plausible claim to have received from Congress authority to decide it.

To the contrary, as the court of appeals pointed out, such questions must be resolved at a political level, where all relevant concerns can be appropriately weighed. See Pet. App. 22a. Prohibition of alcohol occurred by Constitutional amendment. See U.S. Const. amend. XVIII. Prohibition of tobacco would be comparably momentous, and should not be open to decision by a single-mission administrative agency.

2. For nearly 60 years before FDA's tobacco rule-making, the FDCA had been understood by all three branches of government as not granting FDA jurisdiction over tobacco products. The decision below leaves the issue of whether FDA should have jurisdiction over tobacco products where it has always been—with Congress. See Pet. App. 52a-53a.

Whether tobacco products should be subjected to the FDCA is the *kind* of issue that, at any time, would have received full and public congressional consideration before any statutory delegation occurred. Yet, Congress is now said to have delegated to FDA in 1938 new jurisdiction over a major sector of the national economy *unwittingly*. On this issue, the legislative process in 1933-38 included no public notice or discussion, no testimony from interested groups, no debate in either House. An interpretation of the statutory product of that process as resulting in a silent and inadvertent inclusion of tobacco products within the FDCA is not consistent with democratic lawmaking.¹⁶

FDA's position also would override hard-fought legislative processes that have produced the carefully balanced tobacco-specific statutes of the last 34 years. These statutes reflect a political compromise among large and complex interests—relating, *inter alia*, to health, economics, federalism, and informed adult choice. These statutes mark the place where “‘opposing social and political forces have come to rest.’” *Chrysler Corp. v. Brown*, 441 U.S. 281, 313 (1979) (quoting prior decisions).

That this is an issue for Congress is further confirmed by Congress's attentive oversight, and frequent amendment, of both the FDCA and the tobacco-specific statutes.

¹⁶ Under the Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906), FDA (then known as the Bureau of Chemistry in the Department of Agriculture) had taken the position that it had no jurisdiction over tobacco products as customarily marketed. Bureau of Chemistry, U.S. Dep't of Agriculture, Service & Regulatory Announcements, No. 13 (Apr. 2, 1914). Even in broadening the definition of “drug” and adding a parallel definition of “device” in 1938, Congress gave no indication that it intended to change that long-settled position. *Cf. Department of Commerce v. United States House of Representatives*, 119 S. Ct. 765, 779 (1999) (opinion of O'Connor, J., joined by Rehnquist, C.J., & Kennedy, J.).

In the nearly 61 years since enacting the FDCA in 1938, Congress has amended it 57 times, 25 in the last 19 years. See Gerard P. Walsh, Jr., *Federal Food, Drug, and Cosmetic Act With Amendments* iii-iv (GPO 1981) (listing 32 amendments through 1980); 21 U.S.C.A. § 301 Historical & Statutory Notes 33-34 (West Supp. 1998)) (listing 25 amendment since 1980). Congress also has amended its tobacco regulatory program frequently. See pp. 8-9, *supra*.

Finally, the settlements between the tobacco industry and the States, which occurred after FDA's tobacco rule-making, have transformed the environment that prompted FDA to act. The Government is dismissive of the settlements. See Pet. 16, 29, n.9. But Congress is the proper governmental body to evaluate them and to decide whether any additional federal controls—by any agency—are now warranted.

3. The court of appeals' decision is correct. Its method of analysis is fully consistent with the two decisions of this Court most relevant to the kind of statutory construction issue presented here.

First, in accordance with *United States v. Fausto*, 484 U.S. 439, 453 (1988), the court performed “the classic judicial task of reconciling many laws enacted over time, and getting them to ‘make sense’ in combination.” That task “necessarily assumes that the implications of a statute may be altered by the implications of another statute,” and such altering of possible implications is different from a repeal by implication. *Id.*¹⁷

¹⁷ It is also different from preemption. *Cipollone* involved preemption of causes of action under *state law*. The instant case involves preclusion by the tobacco-specific statutes of a wholly new interpretation of a *federal* statute. Therefore, the presumption against preemption, which is based on respect for the sovereignty of the States, is inapplicable here.

Second, in determining the FDCA's applicability by considering what its operative provisions require as well as how its definitions may be read, the court properly followed *Gustafson v. Alloyd Co.*, 513 U.S. 561, 569 (1995) ("Although § 10 does not define what a prospectus is, it does instruct us what a prospectus cannot be if the Act is to be interpreted as a symmetrical and coherent regulatory scheme. . .").

Fausto and *Gustafson* make clear that the Government's reliance on the earlier dictum in *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969), see Pet. 2, 17, is misplaced. The Court there held only that "the literal language" of the FDCA's definition of "drug" does not exclude a therapeutic product that does not touch the body. The court below followed the dictum by treating the FDCA's coverage as being "as broad as its literal language indicates." *Id.* However, the court addressed the language of the whole FDCA, whereas FDA's analysis stopped at the definitions. See Pet. App. 18a-30a.

Bacto-Unidisk cannot displace the analysis mandated at step 1 of *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984), to determine whether the meaning of the statute is clear.

Finally, the *Bacto-Unidisk* dictum does not apply to a situation, like that here, of multiple relevant statutes with different purposes. Section 1331 of the FCLAA declares it to be federal policy to protect commerce and the national economy "to the maximum extent consistent with" the provision of warnings on cigarette packages and in cigarette advertising. The policy of protecting commerce and the national economy presumes the continued distribution of tobacco products. The FDCA, however, requires that drugs and devices found unsafe not be distributed at all. *Bacto-Unidisk* does not address how to

harmonize two such statutes where it is asserted that they apply to the same products.

4. Within the framework of multi-statute analysis, the court of appeals proceeded as *Chevron* directs and correctly resolved the issue before it at step 1. The court did not make any of the three errors attributed to it at Pet. 19-27.

First, to ask at step 1 "whether Congress intended to give the FDA jurisdiction over tobacco products," Pet. App. 15a, was merely to ask "whether Congress has directly spoken to the precise question at issue," i.e., whether "the intent of Congress is clear," *Chevron*, 467 U.S. at 842. The court did not try to read the minds of Members of Congress in 1938. Rather, it properly used textual analysis and other traditional tools of statutory construction.

Second, because the court decided this case at *Chevron* step 1, where no deference is due, its refusal to defer to FDA was proper. See, e.g., *Board of Governors of Fed. Reserve Sys. v. Dimension Fin. Corp.*, 474 U.S. 361, 368 (1986).¹⁸

¹⁸ In its summary of general background principles, the court correctly cited *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649-50 (1990), for the proposition that an agency's interpretation of a statute it does not administer is not entitled to deference at *Chevron* step 2. See Pet. App. 16a. Because the court decided this case at *Chevron* step 1, however, the issue of deference did not arise; and the court had no occasion to rely on *Adams Fruit*. Therefore, the court's reasoning is not circular, as asserted at Pet. 21.

Similarly, contrary to Pet. 22, the court did not decline to defer to FDA on the ground that the agency was seeking to expand its jurisdiction. What the court said was that "ascertaining congressional intent is of particular importance where, as here, an agency is attempting to expand the scope of its jurisdiction." Pet. App. 16a. Ascertaining congressional intent is the task at *Chevron* step 1, where there is no deference; and, under the authorities cited at Pet. App. 16a, the court's statement is correct.

Third, the court's interpretation of the FDCA's operative provisions is faithful to the statutory texts. There is no judicial or FDA interpretation of the FDCA (outside the rulemaking at issue) that permits the continued marketing of any drug or device that has been found unsafe. Contrary to Pet. 23-24, the issue the court decided was not whether FDA's grounds for declining to ban tobacco products are reasonable, but what the FDCA's operative provisions *require*, and whether the relevant statutes, read together and each as a whole, give FDA jurisdiction over tobacco products.¹⁹

The claim that FDA's "interpretation and application of the complex statutory framework at issue lies at the very core of agency action that is entitled to deference," Pet. 18, misreads *Chevron*. *Chevron* step 1 calls for an independent judicial determination of whether the statute addresses the precise issue, 467 U.S. at 842—here, whether Congress delegated to FDA authority to regulate tobacco products. The Government claims that that issue is conclusively resolved by FDA's finding that tobacco products are "intended to affect" the body. Pet. 20. But that self-aggrandizing approach, not supported by any precedent, would nullify the judicial role in determining at step 1 whether the agency's jurisdictional claim is within the authority granted by Congress.²⁰ It would "presume a

¹⁹ Contrary to Pet. 24-25, the court of appeals recognized that an agency may change its interpretation of a statute. See Pet. App. 37a n.18. But, in its step 1 analysis, the court also held, correctly, that an agency may not adopt an interpretation that, as here, conflicts with the clear meaning of the statute, as determined from its text and structure.

²⁰ This extreme delegation argument, first made by the dissent below, see Pet. App. 60a, was properly rejected by the court because "[i]t is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated [to it] by Congress." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988), quoted at Pet. App. 15a.

delegation of power absent an express withholding of such power," and thus "agencies would enjoy virtually limitless hegemony, a result plainly out of keeping with *Chevron* and quite likely with the Constitution as well." *Railway Labor Executives Ass'n v. National Mediation Bd.*, 29 F.3d 655, 671 (D.C. Cir. 1994) (*en banc*).

Resolution of this case at *Chevron* step 1 was especially appropriate in view of the broad issues of policy at its heart. Cf. *Mayburg v. HHS*, 740 F.2d 100, 106-07 (1st Cir. 1984) (Breyer, J.). Here, FDA's assertion of plenary jurisdiction over tobacco products is not the mere filling of a gap to give a statute its congressionally intended scope, but is a reaching out to a wholly different economic sector and a usurpation of a federal policy-making role heretofore exercised solely by Congress. A close examination of the language and structure of the relevant statutes is the proper way to ensure that political accountability remains with Congress, and that agencies do not illegitimately expand their own power.

5. The court of appeals began its analysis by giving weight to a "literal meaning of the statutory definitions" on which FDA relies, taken alone, Pet. App. 18a; but it properly gave greater weight to "the literal definitions in view of the language and structure of the Act as a whole," *id.* at 19a-20a. Here, textual context provides a clear expression of congressional intent. See, e.g., *United Sav. Ass'n v. Timbers of Inwood Forest Assocs., Ltd.*, 484 U.S. 365, 371 (1988) (statutory provision ambiguous in isolation may be clarified by remainder of statutory scheme because only one of the permissible meanings produces a substantive result compatible with the rest of the law). The court examined the FDCA's requirements for genuine medical devices, see Pet. App. 23a-30a, and concluded that "the fact that the operative provisions of the Act simply cannot accommodate tobacco products

[i.e., that FDCA jurisdiction leads to a ban] is a clear indication of congressional intent" not to authorize FDA to regulate them, *id.* at 31a. In sum, as FDA, itself, long recognized, *see* p. 11 & n.9, *supra*, the FDCA was not designed to accommodate a product with the kind of regulatory history and public perception that tobacco had even by the 1930s, or to address the kinds of issues tobacco raises. Indeed, to permit tobacco products to be marketed *under the FDCA* even though FDA has found them unsafe would be to undermine the FDCA's protections against genuine drugs and devices that are unsafe.

Even in 1938 there was no understanding that cigarettes were "safe" as that term is used in the FDCA;²¹ by 1964 the Government's position was that cigarettes have foreseeable "habituat[ing,]" and "pharmacological" effects on the body; and in 1970 Congress required that cigarettes be labeled as "dangerous," their effects on the body having been established by the Surgeon General. *See* pp. 3-4, *supra*. In contrast, since 1938, the FDCA has prohibited the marketing of any drug or medical device that is "dangerous to health." Pub. L. No. 75-717, § 502 (j), 52 Stat. 1040, 1051 (1938), 21 U.S.C. § 352(j). Thus, if cigarettes had been subject to the FDCA, FDA would have had to ban them in 1938 or 1964, but no later than 1970, as "not show[n to be] safe," 21 U.S.C. § 355(d)(2), and as "dangerous," *id.* at § 352(j). However, FDA took no such action.

²¹ For all purposes of the FDCA, a drug or medical device is "safe" when its therapeutic benefits outweigh its risks. Pet. App. 20a-22a. Thus, for example, cancer chemotherapeutic drugs are highly toxic but nevertheless "safe"; a cold remedy with the identical toxicity would be "unsafe." Therefore, FDA's express finding that tobacco products are "unsafe," *see* note 22, *infra*, as a finding not merely that they present risks or are toxic, but that the risks they present are not outweighed by any therapeutic benefits.

In its tobacco rulemaking, FDA found that tobacco products have foreseeable bodily effects. *See* Pet. 3-4. Under FDA's new theory of "intended use," that is a jurisdictional finding, which could have been made at any time since 1964 or even 1938. FDA also found that tobacco products are "unsafe" and "dangerous."²² Under the FDCA, those findings would require a ban. *See* Pet. App. 20a-29a.

The Government states that a ban would be contrary to the public health and absurd for other reasons as well. *See* Pet. 8-9. A ban by FDA would also be contrary to the premise of the tobacco-specific statutes, including FCLAA § 1331, which FDA ignored.²³

After considering the whole FDCA, the court below considered the tobacco-specific statutes. *See* Pet. App. 39a-52a. They demonstrate, through enacted legislation, how Congress intended tobacco products to be regulated with respect to health, underage access, and advertising. Those statutes provide the context for interpretation of the FDCA on the specific issue presented here. *Cf. Department of Commerce v. United States House of Representatives*, 119 S. Ct. 765, 775-78 (1999); *Dunn v. CFTC*, 519 U.S. 465, 475 (1997).

In enacting the tobacco-specific statutes, Congress precluded any new "implication" (even if otherwise permis-

²² 61 Fed. Reg. 44,396, 44,412 (1996); *see also id.* at 44,405; 60 Fed. Reg. 41,314, 41,349 (1995).

²³ The Government quotes the dissent's argument that "[h]ow the FDA has chosen to regulate tobacco has no bearing on the question of whether that agency has the authority to regulate it at all[.] It is no argument to say that the FDA can do nothing because it could have done more." Pet. 24 (quoting Pet. App. 60a-61a). That is not the court's analysis. The analysis is that, if FDA has jurisdiction, it *must* ban tobacco products because it has found them unsafe; and *any* set of regulations short of a ban (not just FDA's current regulations) would be invalid under the FDCA. The dissent disregards the FDCA's operative provisions.

sible), *cf. Fausto*, 484 U.S. at 453, that the FDCA silently delegated to FDA authority to decide to assert jurisdiction over tobacco products and to ban them—the very result Congress rejected in 1965, *see* p. 6, *supra*. “To find authority so explicitly withheld is not merely to disregard in a particular instance the clear will of Congress. It is to disrespect the whole legislative process and the constitutional division of authority between President and Congress.” *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 609 (1952) (Frankfurter, J., concurring).

6. The contention that the FDCA’s definitions apply to “all products not expressly exempted,” Pet. 16, is obviously wrong. That interpretation would, for example, destroy much of the jurisdiction of Consumer Product Safety Commission (“CPSC”). FDA asserts that every product that foreseeably affects the structure or functioning of the body is a “drug” or “device.” However, many consumer products regulated by the CPSC foreseeably affect the structure or functioning of the body (*e.g.*, thermal clothing, air conditioners). Indeed, the CPSC regulates products for the very purpose of reducing their foreseeable harmful effects; but the Consumer Product Safety Act exempts from its coverage “drugs” and “devices,” 15 U.S.C. § 2052(a)(1)(H).

Congress has not given FDA limitless jurisdiction and a roving commission to protect the public health as it sees fit. As this Court observed in *Rodriguez v. United States*, 480 U.S. 522, 525-26 (1987) (*per curiam*) (emphasis in original):

[N]o legislation pursues its purposes at all costs. Deciding what competing values will or will not be sacrificed to the achievement of a particular objective is the very essence of legislative choice—and it frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute’s primary objective must be the law.

The FDCA’s detailed provisions carefully delineate FDA’s authority to regulate specified categories of products. The safety of other categories of products (*e.g.*, automobiles, airplanes, tobacco products, consumer products generally) is addressed by other statutes.²⁴

7. The decision below restores the balance between federal and state roles with respect to tobacco products, which FDA disturbed without a clear statement by Congress. *See, e.g., Gregory v. Ashcroft*, 501 U.S. 452, 460-61 (1991).

Defining and enforcing restrictions on underage access to tobacco products are traditional functions of the States. *See* p. 3, *supra*. FDA’s regulations would supersede such state restrictions and wrest the lead enforcement role from the States. *See* 21 C.F.R. § 897.14. Indeed, under 21 U.S.C. § 360k, all relevant state laws that are different from or in addition to FDA’s regulations are preempted; on application by a State, FDA may waive preemption, but waiver is discretionary. *Id.*

²⁴ The absence of an express exemption in the FDCA for tobacco products is fully explained by HEW’s and FDA’s testimony to Congress in 1964-65. *See* pp. 5-6, *supra*. Some matters are so clear that no express provision is needed. *See, e.g., NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 283 (1974); *Argentine Republic v. Amerasia Hess Shipping Corp.*, 488 U.S. 428, 437 (1989) (“we doubt that even the most meticulous draftsman would have concluded that Congress also needed to amend *pro tanto* the [earlier statute]”).

The Government’s citation of 21 U.S.C. § 321(ff)(1), *see* Pet. 17, 22, is inapposite. In the dietary supplement legislation, Pub. L. No. 103-417, § 3, 108 Stat. 4325, 4327 (1994), Congress excluded tobacco from the new definition of “dietary supplement.” The subject before Congress in 1994 was dietary supplements. Congress merely excluded from that legislative process the contending interests on the unrelated question of FDA jurisdiction over tobacco products. From Congress’s limited action in 1994, no inference one way or the other can properly be drawn with respect to that unrelated question.

Under FDA's regulations, every improper sale or failure to verify the age of a purchaser in a local convenience store or gas station is a federal offense, 21 C.F.R. § 897.1(b); 21 U.S.C. § 331(b),(k), punishable by prosecution in federal district court, *id.* § 333(a)(1), or by civil penalty imposed by FDA and reviewable in the federal courts of appeals, *id.* § 333(g). The creator of this potentially massive expansion of federal civil and criminal jurisdiction is not Congress, but FDA.²⁵

There is no clear congressional statement authorizing FDA to supersede state laws on underage access, to create federal criminal or civil penalty liability for violations of restrictions on underage access, or to shift the lead enforcement role from the States to the federal government. To the contrary, the 1992 tobacco statute seeks to strengthen the State role. *See pp. 8-9, supra.* That some States may welcome this transfer of responsibility to the federal government does not provide Congressional sanction for the federalization of traditional state functions.

CONCLUSION

The petition for a writ of certiorari should be denied.

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²⁵ The expansion of federal jurisdiction is not merely theoretical. FDA has already initiated civil penalty proceedings that allege local violations of FDA's sales and age-verification requirements. Telephone Conversation with Deputy Branch Chief, FDA Dockets Management Branch (Feb. 22, 1999).

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OCTOBER TERM, 1998

FOOD AND DRUG ADMINISTRATION, *et al.*,
Petitioners,

v.

BROWN AND WILLIAMSON TOBACCO CORP., *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the
United States Court of Appeals
for the Fourth Circuit

APPENDIX TO
RESPONDENTS' BRIEF IN OPPOSITION TO
PETITION FOR A WRIT OF CERTIORARI

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APPENDIX

**PUBLIC LAWS AND
STATUTORY PROVISIONS**

Public Law 89-92
89th Congress

AN ACT

To regulate the labeling of cigarettes,
and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Federal Cigarette Labeling and Advertising Act".

DECLARATION OF POLICY

SEC. 2. It is the policy of the Congress, and the purpose of this Act, to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby—

(1) the public may be adequately informed that cigarette smoking may be hazardous to health by inclusion of a warning to that effect on each package of cigarettes; and

(2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.

DEFINITIONS

SEC. 3. As used in this Act—

(1) The term "cigarette" means—

2a

(A) any roll of tobacco wrapped in paper or any substance not containing tobacco, and

(B) any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in subparagraph (A).

(2) The term "commerce" means (A) commerce between any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island and any place outside thereof; (B) commerce between points in any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island, but through any place outside thereof; or (C) commerce wholly within the District of Columbia, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island.

(3) The term "United States", when used in a geographical sense, includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, and Johnston Island.

(4) The term "package" means a pack, box, carton, or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers.

(5) The term "person" means an individual, partnership, corporation, or any other business or legal entity.

3a

(6) The term "sale or distribution" includes sampling or any other distribution not for sale.

LABELING

SEC. 4. It shall be unlawful for any person to manufacture, import, or package for sale or distribution within the United States any cigarettes the package of which fails to bear the following statement: "Caution: Cigarette Smoking May Be Hazardous to Your Health." Such statement shall be located in a conspicuous place on every cigarette package and shall appear in conspicuous and legible type in contrast by typography, layout, or color with other printed matter on the package.

PREEMPTION

SEC. 5. (a) No statement relating to smoking and health, other than the statement required by section 4 of this Act, shall be required on any cigarette package.

(b) No statement relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.

(c) Except as is otherwise provided in subsections (a) and (b), nothing in this Act shall be construed to limit, restrict, expand, or otherwise affect, the authority of the Federal Trade Commission with respect to unfair or deceptive acts or practices in the advertising of cigarettes, nor to affirm or deny the Federal Trade Commission's holding that it has the authority to issue trade regulation rules or to require an affirmative statement in any cigarette advertisement.

(d)(1) The Secretary of Health, Education, and Welfare shall transmit a report to the Congress not later than

eighteen months after the effective date of this Act, and annually thereafter, concerning (A) current information on the health consequences of smoking and (B) such recommendations for legislation as he may deem appropriate.

(2) The Federal Trade Commission shall transmit a report to the Congress not later than eighteen months after the effective date of this Act, and annually thereafter, concerning (A) the effectiveness of cigarette labeling, (B) current practices and methods of cigarette advertising and promotion, and (C) such recommendations for legislation as it may deem appropriate.

CRIMINAL PENALTY

SEC. 6. Any person who violates the provisions of this Act shall be guilty of a misdemeanor and shall on conviction thereof be subject to a fine of not more than \$10,000.

INJUNCTION PROCEEDINGS

SEC. 7. The several district courts of the United States are invested with jurisdiction, for cause shown, to prevent and restrain violations of this Act upon the application of the Attorney General of the United States acting through the several United States attorneys in their several districts.

CIGARETTES FOR EXPORT

SEC. 8. Packages of cigarettes manufactured, imported, or packaged (1) for export from the United States or (2) for delivery to a vessel or aircraft, as supplies, for consumption beyond the jurisdiction of the internal revenue laws of the United States shall be exempt from the requirements of this Act, but such exemptions shall not apply to cigarettes manufactured, imported, or packaged for sale or distribution to members or units of the Armed

Forces of the United States located outside of the United States.

SEPARABILITY

SEC. 9. If any provision of this Act or the application thereof to any person or circumstances is held invalid, the other provisions of this Act and the application of such provision to other persons or circumstances shall not be affected thereby.

TERMINATION OF PROVISIONS AFFECTING REGULATION OF ADVERTISING

SEC. 10. The provisions of this Act which affect the regulation of advertising shall terminate on July 1, 1969, but such termination shall not be construed as limiting, expanding, or otherwise affecting the jurisdiction or authority which the Federal Trade Commission or any other Federal agency had prior to the date of enactment of this Act.

EFFECTIVE DATE

SEC. 11. This Act shall take effect on January 1, 1966.

Approved July 27, 1965.

Public Law 91-222
91st Congress

AN ACT

To extend public health protection with respect to cigarette smoking and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Public Health Cigarette Smoking Act of 1969".

SEC. 2. Sections 2 through 10 of Public Law 89-92 (15 U.S.C. 1331-1338) are amended to read as follows:

"DECLARATION OF POLICY

"SEC. 2. It is the policy of the Congress, and the purpose of this Act, to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby—

"(1) the public may be adequately informed that cigarette smoking may be hazardous to health by inclusion of a warning to that effect on each package of cigarettes; and

"(2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.

"DEFINITIONS

"SEC. 3. As used in this Act—

"(1) The term 'cigarette' means—

"(A) any roll of tobacco wrapped in paper or in any substance not containing tobacco, and

"(B) any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in subparagraph (A).

"(2) The term 'commerce' means (A) commerce between any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island and any place outside thereof; (B) commerce between points in any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island, but through any place outside thereof; or (C) commerce wholly within the District of Columbia, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island.

"(3) The term 'United States', when used in a geographical sense, includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, and Johnston Island. The term 'State' includes any political division of any State.

"(4) The term 'package' means a pack, box, carton, or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers.

"(5) The term 'person' means an individual, partnership, corporation, or any other business or legal entity.

"(6) The term 'sale or distribution' includes sampling or any other distribution not for sale.

"LABELING

"SEC. 4. It shall be unlawful for any person to manufacture, import, or package for sale or distribution within the United States any cigarettes the package of which fails to bear the following statement: 'Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health'. Such statement shall be located in a conspicuous place on every cigarette package and shall appear in conspicuous and legible type in contrast by typography, layout, or color with other printed matter on the package.

"PREEMPTION

"SEC. 5. (a) No statement relating to smoking and health, other than the statement required by section 4 of this Act, shall be required on any cigarette package.

"(b) No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.

"UNLAWFUL ADVERTISEMENTS

"SEC. 6. After January 1, 1971, it shall be unlawful to advertise cigarettes on any medium of electronic communication subject to the jurisdiction of the Federal Communications Commission.

"FEDERAL TRADE COMMISSION

"SEC. 7. (a) The Federal Trade Commission shall not take any action before July 1, 1971, with respect to its

pending trade regulation rule proceeding relating to cigarette advertising. If at any time on or after July 1, 1971, the Federal Trade Commission determines it is necessary to take action with respect to such pending trade regulation rule proceeding, it shall notify the Congress of the determination. Such notification shall include the text of the trade regulation rule and a full statement of the basis for such determination. No trade regulation rule adopted in such proceeding may take effect until six months after the Commission has notified the Congress of the text of such rule, in order that the Congress may act if it so desires.

"(b) Except as provided in subsection (a), nothing in this Act shall be construed to limit, restrict, expand, or otherwise affect the authority of the Federal Trade Commission with respect to unfair or deceptive acts or practices in the advertising of cigarettes.

"(c) Nothing in this Act shall be construed to affirm or deny the Federal Trade Commission's holding that it has the authority to issue trade regulation rules or to require an affirmative statement in any cigarette advertisement.

"REPORTS

"SEC. 8. (a) The Secretary of Health, Education, and Welfare shall transmit a report to the Congress not later than January 1, 1971, and annually thereafter, concerning (A) current information in the health consequences of smoking, and (B) such recommendations for legislation as he may deem appropriate.

"(b) The Federal Trade Commission shall transmit a report to the Congress not later than January 1, 1971, and annually thereafter, concerning (A) the effectiveness of cigarette labeling, (B) current practices and methods

of cigarette advertising and promotion, and (C) such recommendations for legislation as it may deem appropriate.

"CRIMINAL PENALTY

"SEC. 9. Any person who violates the provisions of this Act shall be guilty of a misdemeanor and shall on conviction thereof be subject to a fine of not more than \$10,000.

"INJUNCTION PROCEEDINGS

"SEC. 10. The several district courts of the United States are invested with jurisdiction, for cause shown, to prevent and restrain violations of this Act upon the application of the Attorney General of the United States acting through the several United States attorneys in their several districts.

"CIGARETTES FOR EXPORT

"SEC. 11. Packages of cigarettes manufactured, imported, or packaged (1) for export from the United States or (2) for delivery to a vessel or aircraft, as supplies, for consumption beyond the jurisdiction of the internal revenue laws of the United States shall be exempt from the requirements of this Act, but such exemptions shall not apply to cigarettes manufactured, imported, or packaged for sale or distribution to members or units of the Armed Forces of the United States located outside of the United States.

"SEPARABILITY

"SEC. 12. If any provision of this Act or the application thereof to any person or circumstances is held invalid, the other provisions of this Act and the application of such provision to other persons or circumstances shall not be affected thereby."

SEC. 3. Section 5 of the amendment made by this Act shall take effect as of July 1, 1969. Section 4 of the amendment made by this Act shall take effect on the first day of the seventh calendar month which begins after the date of the enactment of this Act. All other provisions of the amendment made by this Act except where otherwise specified shall take effect on January 1, 1970.

Approved April 1, 1970.

Public Law 98-24
98th Congress

ALCOHOL AND DRUG ABUSE AMENDMENTS OF 1983

An Act to remedy alcohol and drug abuse.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE; STATEMENT OF POLICY

SECTION 1. (a) This Act may be cited as the "Alcohol and Drug Abuse Amendments of 1983".

(b) It is the policy of the United States and the purpose of this Act to provide leadership in the national effort to reduce the incidence of alcoholism and alcohol-related problems and drug abuse through—

(1) a continued Federal commitment to research into the behavioral and biomedical etiology, the treatment, and the mental and physical health and social and economic consequences of alcohol abuse and alcoholism and drug abuse;

(2) a commitment to—

(A) extensive dissemination to States, units of local government, community organizations, and private groups of the most recent information and research findings with respect to alcohol abuse and alcoholism and drug abuse, including information with respect to the application of research findings; and

(B) the accomplishment of such dissemination through up-to-date publications, demonstrations, educational programs, and other appropriate means;

(3) the provision of technical assistance to research personnel; services personnel, and prevention personnel in the field of alcohol abuse and alcoholism and drug abuse;

(4) the development and encouragement of prevention programs designed to combat the spread of alcoholism, alcohol abuse, drug abuse, and the abuse of other legal and illegal substances;

(5) the development and encouragement of effective occupational prevention and treatment programs within Government and in cooperation with the private sector; and

(6) the provision of a Federal response to alcohol abuse and alcoholism and drug abuse which encourages the greatest participation by the private sector, both financially and otherwise, and concentrates on carrying out functions relating to alcohol abuse and alcoholism and drug abuse which are truly national in scope.

THE ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION AND THE NA- TIONAL INSTITUTE OF MENTAL HEALTH, THE NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM, AND THE NATIONAL IN- STITUTE ON DRUG ABUSE

SEC. 2. (a)(1) Title V of the Public Health Service Act is transferred to the end of the Public Health Service Act and redesignated as title XXI and sections 501 through 515 are redesignated as sections 2101 through 2115, respectively.

(2) Sections 217(c), 217(d), and 384 of the Public Health Service Act (42 U.S.C. 218 and 278) are each

amended by striking out "501" and inserting in lieu thereof "2101".

(b)(1) The Public Health Service Act is amended by inserting after title IV a new title designated as follows:

"TITLE V—ADMINISTRATION AND COORDINATION OF THE NATIONAL INSTITUTE OF MENTAL HEALTH, THE NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM, AND THE NATIONAL INSTITUTE ON DRUG ABUSE

"PART A—ADMINISTRATION AND INSTITUTES".

(2) Section 210 of the Act of May 14, 1974 (42 U.S.C. 3511) is transferred to title V of the Public Health Service Act established by paragraph (1), redesignated as section 501, and amended—

(A) by striking out "of Health, Education, and Welfare" each place it occurs;

(B) in subsection (c), by striking out "of the Public Health Service Act";

(C) by amending subsection (d) to read as follows:

"(d) To educate the public with respect to the health hazards of alcoholism, alcohol abuse, and drug abuse, the Administrator shall take such actions as may be necessary to ensure the widespread dissemination of current publications of the National Institute on Alcohol Abuse and Alcoholism and the National Institute on Drug Abuse relating to the most recent research findings with respect to such health hazards.";

(D) by adding at the end the following:

"(e)(1) There shall be in the administration an Associate Administrator for Prevention to whom the Adminis-

trator shall delegate the function of promoting the prevention research programs of the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse and coordinating such programs between the institutes and between the institutes and other public and private entities.

"(2) On or before January 1, 1984, and annually thereafter, the Administrator, acting through the Associate Administrator for Prevention, shall submit to the Congress a report describing the prevention activities (including preventive medicine and health promotion) undertaken by the administration, the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse. The report shall include a detailed statement of the expenditures made for the activities reported on and the personnel used in connection with such activities.

"(f) The Administrator shall establish a process for the prompt and appropriate response to information provided the Administrator respecting (1) scientific fraud in connection with projects for which funds have been made available under this Act, and (2) incidences of violations of the rights of human subjects of research for which funds have been made available under this title. The process shall include procedures for the receiving of reports of such information from recipients of funds under this title and taking appropriate action with respect to such fraud and violations."

(3) Section 101 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 is transferred to title V of the Public Health Service Act, inserted after the section 501 inserted by paragraph (2), redesignated as section 502, and amended—

(A) in subsection (a)—

(i) by striking out “this Act” the first time it occurs and inserting in lieu thereof “this section”,

(ii) by striking out “assigned to the Secretary of Health and Human Services (hereafter in this Act referred to as the ‘Secretary’)” and inserting in lieu thereof “relating to alcohol abuse and alcoholism assigned to the Secretary”, and

(iii) by striking out “of the Public Health Service Act”, and

(B) by amending the section heading to read as follows:

**“NATIONAL INSTITUTE ON ALCOHOL ABUSE
AND ALCOHOLISM”.**

(4) Section 501 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act is transferred to title V of the Public Health Service Act, inserted after the section 502 inserted by paragraph (3), redesignated as section 503, and amended—

(A) in subsection (a)—

(i) by inserting “SEC. 503.” before “(a)”,

(ii) by striking out “this title” and inserting in lieu thereof “this section”,

(iii) by striking out “of the Secretary of Health and Human Services (hereinafter in this title referred to as the ‘Secretary’) with respect to drug abuse prevention functions” and inserting in lieu thereof “relating to drug abuse assigned to the Secretary by this Act”, and

(iv) by striking out “of the Public Health Service Act”,

(B) by striking out “(hereinafter in this title referred to as the ‘Director’)” in subsection (b)(1), and

(C) by striking out the section heading

“§ 501. Establishment of Institute”.

and inserting in lieu thereof the following:

“NATIONAL INSTITUTE ON DRUG ABUSE”.

(5) Subsection (a) of section 406 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act is transferred to section 503 (as so redesignated), inserted after subsection (d), and redesignated as subsection (e).

(6) Section 455 of the Public Health Service Act is inserted in title V of the Public Health Service Act after the section 503 inserted by paragraph (4) of this subsection and redesignated as section 504.

(7) The following sections are inserted in title V of the Public Health Service Act after the section 504 inserted by paragraph (6):

**“REPORTS ON ALCOHOLISM, ALCOHOL ABUSE,
AND DRUG ABUSE**

“SEC. 505. (a) The Secretary shall submit to Congress on or before January 15, 1984, and every three years thereafter a report—

“(1) containing current information on the health consequences of using alcoholic beverages,

“(2) containing a description of current research findings made with respect to alcohol abuse and alcoholism, and

"(3) containing such recommendations for legislation and administrative action as the Secretary may deem appropriate.

"(b) The Secretary shall submit to Congress on or before January 15, 1984, and every three years thereafter a report—

"(1) describing the health consequences and extent of drug abuse in the United States;

"(2) describing current research findings made with respect to drug abuse, including current findings on the health effects of marihuana and the addictive property of tobacco; and

"(3) containing such recommendations for legislation and administrative action as the Secretary may deem appropriate.

"PEER REVIEW

"SEC. 506. (a) The Secretary, after consultation with the Directors of the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse shall by regulation require appropriate technical and scientific peer review of biomedical and behavioral research and development grants, cooperative agreements, and contracts to be administered through the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse.

"(b) Regulations promulgated under subsection (a) shall require that the review of grants, cooperative agreements, and contracts required by the regulations be conducted—

"(1) in a manner consistent with the system for scientific peer review applicable on the date of the

enactment of this section to grants, cooperative agreements, and contracts under this Act for biomedical and behavioral research, and

"(2) to the extent practical, by peer review groups performing such review on or before such date.

"(c) The members of any peer review group established under such regulations shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of the group and not more than one-fourth of the members of any peer review group established under such regulations shall be officers or employees of the United States.

"(d) The Administrator of the administration shall establish procedures for periodic, technical, and scientific peer review of research at the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse. Such procedures shall require that—

"(1) the reviewing entity be provided a written description of the research to be reviewed; and

"(2) the reviewing entity provide the advisory council of the institute involved with such description and the results of the review by the entity."

(8) The following heading is inserted in title V of the Public Health Service Act after the section 506 inserted by paragraph (7):

"PART B—RESEARCH

"Subpart 1—Alcohol Abuse and Alcoholism".

(9) Sections 501, 503, and 504 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 are transferred to the

subpart 1 of Part B of title V of the Public Health Service Act established by paragraph (8), redesignated as sections 510, 511, and 512, respectively, and amended as follows:

(A) Section 510 (as so redesignated) is amended—

(i) by striking out “the Institute” in subsection (a) and inserting in lieu thereof “the National Institute on Alcohol Abuse and Alcoholism (hereinafter in this subpart referred to as the ‘Institute’)”,

(ii) by striking out “make available through publications and other appropriate means” in subsection (b)(1) and inserting in lieu thereof “disseminate through publications and other appropriate means (including the development of curriculum materials)”,

(iii) by striking “; and such Council shall give” and all that follows in subsection (b)(3) and inserting in lieu thereof the following “, giving special consideration to projects relating to—

“(A) the relationship between alcohol abuse and domestic violence,

“(B) the effects of alcohol use during pregnancy,

“(C) the impact of alcoholism and alcohol abuse on the family, the workplace, and systems for the delivery of health services,

“(D) the relationship between the abuse of alcohol and other drugs,

“(E) the effect on the incidence of alcohol abuse and alcoholism of social pressures, legal requirements respecting the use of alcoholic beverages, the cost of such beverages, and the economic status and education of users of such beverages,

“(F) the interrelationships between alcohol use and other health problems, and

“(G) the comparison of the cost and effectiveness of various treatment methods for alcoholism and alcohol abuse and the effectiveness of prevention and intervention programs for alcoholism and alcohol abuse.”,

(iv) by inserting “or the impact of alcohol abuse on other health problems” before the semicolon in subsection (b)(5), and

(v) by amending the section heading to read as follows:

**“ALCOHOL ABUSE AND
ALCOHOLISM RESEARCH”.**

(B) Section 511 (as so redesignated) is amended—

(i) by striking out the last sentence of subsection (a),

(ii) by striking out the second sentence of subsection (b),

(iii) by striking out “of the Public Health Service Act (42 U.S.C. 292a)” in subsection (b), and

(iv) by striking out subsection (c).

(C) Section 512 (as so redesignated) is amended to read as follows:

"AUTHORIZATION OF APPROPRIATIONS

"SEC. 512. There are authorized to be appropriated to carry out this subpart \$33,484,000 for fiscal year 1983 and \$45,790,000 for fiscal year 1984. Of the funds appropriated under this section for any fiscal year, not more than 35 per centum may be obligated for grants under section 511."

(10) The following heading is inserted in title V of the Public Health Service Act after the section 512 inserted by paragraph (9):

"Subpart 2—Drug Abuse Research".

(11) Section 503 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act is transferred to the subpart 2 of part B of title V established by paragraph (10), redesignated as section 515, and amended—

(A) by striking out "The Director" the first time it occurs in subsection (a) and inserting in lieu thereof "The Director of the National Institute on Drug Abuse",

(B) by amending subsection (b) to read as follows:

"(b) In carrying out the activities described in subsection (a), the Secretary, acting through the Institute, may—

"(1) collect and disseminate through publications and other appropriate means, including the development of curriculum materials, information as to, and the practical application of, the research and other activities under this section,

"(2) make grants or enter into contracts with individuals and public and nonprofit entities for the purpose of determining the causes of drug abuse in a particular area, and

"(3) make grants to and enter into contracts with individuals and public and private nonprofit entities for research respecting improved drug maintenance and detoxification techniques and programs."

(C) by amending subsection (c) to read as follows:

"(c) For the purposes of subsections (a) and (b), there are authorized to be appropriated \$47,374,000 for fiscal year 1983 and \$56,160,000 for fiscal year 1984."

(D) by striking out the section heading and inserting in lieu thereof the following:

"DRUG ABUSE RESEARCH",

and

(E) by inserting before "(a)" in subsection (a) the following: "SEC. 515."

(12) The following headings are inserted in title V of the Public Health Service Act after the section 515 inserted by paragraph (11):

**"PART C—MISCELLANEOUS PROVISIONS
RELATING TO ALCOHOL ABUSE AND
ALCOHOLISM AND DRUG ABUSE**

**"Subpart 1—Provisions Relating to Alcohol Abuse
and Alcoholism".**

(13) Sections 201, 301, 321, and 333 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treat-

ment, and Rehabilitation Act of 1970 are transferred to the part C of title V established by paragraph (12), redesignated as sections 520, 521, 522, and 523, respectively, and amended as follows:

(A) Section 520 (as so redesignated) is amended—

(i) by striking out “the Institute” in subsection (a) and inserting in lieu thereof “the National Institute on Alcohol Abuse and Alcoholism”,

(ii) by striking out “section 321” in subsection (a)(4) and inserting in lieu thereof “section 522”, and

(iii) by striking out “under this Act and under the Drug Abuse Prevention, Treatment, and Rehabilitation Act” and inserting in lieu thereof “under this title”.

(B) Section 521 (as so redesignated) is amended—

(i) by striking out “section 413(b) of the Drug Abuse Prevention, Treatment, and Rehabilitation Act” in subsection (b)(4) and inserting in lieu thereof “section 525”,

(ii) by striking out “title” in subsection (d) and inserting in lieu thereof “section”, and

(iii) by striking out subsection (e).

(C) Section 522 (as so redesignated) is amended by striking out “of the Public Health Service Act” in subsection (a).

(14) The following heading is inserted in part C of title V of the Public Health Service Act after section 523 (as so redesignated):

“Subpart 2—Provisions Relating to Drug Abuse”.

(15) Section 502 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act is transferred to title V of the Public Health Service Act, inserted after the heading inserted by paragraph (14), redesignated as section 524, and amended—

(A) by striking out “The Director” in subsection (a) and inserting in lieu thereof “The Director of the National Institute on Drug Abuse”,

(B) by striking out “, to promote the purposes of this Act,” in subsection (b)(2),

(C) by striking out “section 407” in subsection (d) and inserting in lieu thereof “section 526”,

(D) by striking out “under this Act and under the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970” in subsection (d) and inserting in lieu thereof “under this title”,

(E) by striking out the section heading and inserting in lieu thereof:

“TECHNICAL ASSISTANCE TO STATE
AND LOCAL AGENCIES”,

and

(F) by inserting before “(a)” in subsection (a) the following: “SEC. 524.”:

(16)(A) Section 413 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act is transferred to title V of the Public Health Service Act, inserted after the section 524 inserted by paragraph (15), redesignated as section 525, and amended—

(i) by striking out the section heading and inserting in lieu thereof:

**"DRUG ABUSE AMONG GOVERNMENT
AND OTHER EMPLOYEES";**

(ii) by inserting before "(a)" the following: "SEC. 525."; and

(iii) by striking out "section 201(b) of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970" in subsection (b)(4) and inserting in lieu thereof "section 521".

(B) Section 407 and 408 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act are transferred to title V of the Public Health Service Act, inserted after the section 525 inserted by subparagraph (A), redesignated as sections 526 and 527 and amended as follows:

(i) Section 526 (as so redesignated) is amended—

(I) by striking out the section heading and inserting in lieu thereof:

**"ADMISSION OF DRUG ABUSERS TO
PRIVATE AND PUBLIC HOSPITALS";**

and

(II) by inserting before "(a)" in subsection (a) the following: "SEC. 526.".

(ii) Section 527 (as so redesignated) is amended—

(I) by striking out the section heading and inserting in lieu thereof:

**"CONFIDENTIALITY OF PATIENT
RECORDS";**

(II) by inserting before "(a)" in subsection (a) the following: "SEC. 527."; and

(III) by striking out "of Health and Human Services" in subsection (g).

(c)(1) Sections 102, 103, and 502 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 are repealed.

(2) Sections 405 and 504 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act are repealed.

(d) Title V of the Medical Facilities Construction and Modernization Amendments of 1970 (Public Law 91-296) is repealed.

**ALCOHOL AND DRUG ABUSE AND MENTAL
HEALTH REPORTS BY THE SECRETARY**

SEC. 3. (a) The Secretary of Health and Human Services shall submit to the Congress on or before January 15, 1984, a report describing the extent to which Federal and State programs, departments, and agencies are concerned and are dealing effectively with—

- (1) the problems of alcohol abuse and alcoholism,
- (2) the problems of drug abuse, and
- (3) mental illness.

(b) The report required by subsection (a) shall include information with respect to the services provided for alcohol abuse, alcoholism, drug abuse, and mental health under part B of title XIX of the Public Health Service Act. To obtain information respecting such services, the Secretary shall work with appropriate national organizations to en-

sure that State and local governments use compatible means of collecting data respecting such services so that uniform national data with respect to the provisions of such services will be available to the States and to the Secretary.

(c) In compiling data for the report required by subsection (a), the Secretary may not require any State to submit any information which is not required under section 1916 (a) of the Public Health Service Act.

DRUG ABUSE STRATEGY REPORT

SEC. 4. (a) Section 305 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1165) is amended to read as follows:

"§ 305. Report

"The President shall submit to the Congress on or before August 1, 1984, and every two years thereafter, a written report describing the strategy. The report shall specify the objectives, nature, and results of the strategy and shall contain an accounting of funds expended under title II."

(b) Section 207 of such Act (21 U.S.C. 1117) is repealed.

MISCELLANEOUS

SEC. 5. (a)(1) Section 311(c)(4) of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4577(c)(4)) is amended by inserting "(including Native Hawaiians and Native American Pacific Islanders)" after "Native Americans".

(2) Section 18(b)(10) of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act Amendments of 1979 (42 U.S.C. 4541

note) is amended by inserting "Native Hawaiians, Native American Pacific Islanders," after "Alaskan Natives,".

(3) Section 410(d) of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1177(d)) is amended by striking out "native Americans" and inserting in lieu thereof "Native Americans (including Native Hawaiians and Native American Pacific Islanders)".

(b) Section 475(a) of the Public Health Service Act (42 U.S.C. 2981-4(a)) is amended (1) by striking out "the Directors of the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse and", and (2) by striking out ", the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse," in paragraph (2).

Approved April 26, 1983.

Public Law 98-474
98th Congress

An Act

To establish a national program to increase the availability of information on the health consequences of smoking, to amend the Federal Cigarette Labeling and Advertising Act to change the label requirements for cigarettes, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE

SECTION 1. This Act may be cited as the "Comprehensive Smoking Education Act".

PURPOSE

SEC. 2. It is the purpose of this Act to provide a new strategy for making Americans more aware of any adverse health effects of smoking, to assure the timely and widespread dissemination of research findings and to enable individuals to make informed decisions about smoking.

SMOKING RESEARCH, EDUCATION, AND INFORMATION

SEC. 3. (a) The Secretary of Health and Human Services (hereinafter in this section referred to as the "Secretary") shall establish and carry out a program to inform the public of any dangers to human health presented by cigarette smoking. In carrying out such program, the Secretary shall—

(1) conduct and support research on the effect of cigarette smoking on human health and develop materials for informing the public of such effect;

(2) coordinate all research and educational programs and other activities within the Department of Health and Human Services (hereinafter in this section referred to as the "Department") which relate to the effect of cigarette smoking on human health and coordinate, through the Interagency Committee on Smoking and Health (established under subsection (b)), such activities with similar activities of other Federal agencies and of private agencies;

(3) establish and maintain a liaison with appropriate private entities, other Federal agencies, and State and local public agencies respecting activities relating to the effect of cigarette smoking on human health;

(4) collect, analyze, and disseminate (through publications, bibliographies, and otherwise) information, studies, and other data relating to the effect of cigarette smoking on human health, and develop standards, criteria, and methodologies for improved information programs related to smoking and health;

(5) compile and make available information on State and local laws relating to the use and consumption of cigarettes; and

(6) undertake any other additional information and research activities which the Secretary determines necessary and appropriate to carry out this section.

(b)(1) To carry out the activities described in paragraphs (2) and (3) of subsection (a) there is established an Interagency Committee on Smoking and Health. The Committee shall be composed of—

(A) members appointed by the Secretary from appropriate institutes and agencies of the Depart-

ment, which may include the National Cancer Institute, the National Heart, Lung, and Blood Institute, the National Institute of Child Health and Human Development, the National Institute on Drug Abuse, the Health Resources and Services Administration, and the Centers for Disease Control;

(B) at least one member appointed from the Federal Trade Commission, the Department of Education, the Department of Labor, and any other Federal agency designated by the Secretary, the appointment of whom shall be made by the head of the entity from which the member is appointed; and

(C) five members appointed by the Secretary from physicians and scientists who represent private entities involved in informing the public about the health effects of smoking.

The Secretary shall designate the chairman of the Committee.

(2) While away from their homes or regular places of business in the performance of services for the Committee, members of the Committee shall be allowed travel expenses, including per diem in lieu of subsistence, in the manner provided by sections 5702 and 5703 of title 5 of the United States Code.

(3) The Secretary shall make available to the Committee such staff, information, and other assistance as it may require to carry out its activities effectively.

(c) The Secretary shall transmit a report to Congress not later than January 1, 1985, and biennially thereafter which shall contain—

(1) an overview and assessment of Federal activities undertaken to inform the public of the health

consequences of smoking and the extent of public knowledge of such consequences,

(2) a description of the Secretary's and Committee's activities under subsection (a),

(3) information regarding the activities of the private sector taken in response to the effects of smoking on health, and

(4) such recommendations as the Secretary may consider appropriate.

LABELS FOR CIGARETTES AND CIGARETTE ADVERTISING

SEC. 4. (a) Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) is amended to read as follows:

"LABELING

"SEC. 4. (a)(1) It shall be unlawful for any person to manufacture, package, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:

"SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.

"SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.

"SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.

"SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

"(2) It shall be unlawful for any manufacturer or importer of cigarettes to advertise or cause to be advertised (other than through the use of outdoor billboards) within the United States any cigarette unless the advertising bears, in accordance with the requirements of this section, one of the following labels:

"SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.

"SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.

"SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.

"SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

"(3) It shall be unlawful for any manufacturer or importer of cigarettes to advertise or cause to be advertised within the United States through the use of outdoor billboards any cigarette unless the advertising bears, in accordance with the requirements of this section, one of the following labels:

"SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, And Emphysema.

"SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Health Risks.

"SURGEON GENERAL'S WARNING: Pregnant Women Who Smoke Risk Fetal Injury And Premature Birth.

"SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

"(b)(1) Each label statement required by paragraph (1) of subsection (a) shall be located in the place label statements were placed on cigarette packages as of the date of the enactment of this subsection. The phrase 'Surgeon General's Warning' shall appear in capital letters and the size of all other letters in the label shall be the same as the size of such letters as of such date of enactment. All the letters in the label shall appear in conspicuous and legible type in contrast by typography, layout, or color with all other printed material on the package.

"(2) The format of each label statement required by paragraph (2) of subsection (a) shall be the format required for label statements in cigarette advertising as of the date of the enactment of this subsection, except that the phrase 'Surgeon General's Warning' shall appear in capital letters, the area of the rectangle enclosing the label shall be 50 per centum larger in size with a corresponding increase in the size of the type in the label, the width of the rule forming the border around the label shall be twice that in effect on such date, and the label may be placed at a distance from the outer edge of the advertisement which is one-half the distance permitted on such date. Each label statement shall appear in conspicuous and legible type in contrast by typography, layout, or color with all other printed material in the advertisement.

"(3) The format and type style of each label statement required by paragraph (3) of subsection (a) shall be the format and type style required in outdoor billboard advertising as of the date of the enactment of this subsection. Each such label statement shall be printed in capital letters

of the height of the tallest letter in a label statement on outdoor advertising of the same dimension on such date of enactment. Each such label statement shall be enclosed by a black border which is located within the perimeter of the format required in outdoor billboard advertising of the same dimension on such date of enactment and the width of which is twice the width of the vertical element of any letter in the label statement within the border.

“(c) The label statements specified in paragraphs (1), (2), and (3) of subsection (a) shall be rotated by each manufacturer or importer of cigarettes quarterly in alternating sequence on packages of each brand of cigarettes manufactured by the manufacturer or importer and in the advertisements for each such brand of cigarettes in accordance with a plan submitted by the manufacturer or importer and approved by the Federal Trade Commission. The Federal Trade Commission shall approve a plan submitted by a manufacturer or importer of cigarettes which will provide the rotation required by this subsection and which assures that all of the labels required by paragraphs (1), (2), and (3) will be displayed by the manufacturer or importer at the same time.

“(d) Subsection (a) does not apply to a distributor or a retailer of cigarettes who does not manufacture, package, or import cigarettes for sale or distribution within the United States.”.

(b) The amendment made by subsection (a) shall take effect upon the expiration of a one-year period beginning on the date of the enactment of this Act.

CIGARETTE INGREDIENTS

SEC. 5. (a) The Federal Cigarette Labeling and Advertising Act is amended by redesignating sections 7 through

12 as sections 8 through 13, respectively, and by inserting after section 6 the following new section:

“CIGARETTE INGREDIENTS

“SEC. 7. (a) Each person who manufactures, packages, or imports cigarettes shall annually provide the Secretary with a list of the ingredients added to tobacco in the manufacture of cigarettes which does not identify the company which uses the ingredients or the brand of cigarettes which contain the ingredients. A person or group of persons required to provide a list by this subsection may designate an individual or entity to provide the list required by this subsection.

“(b)(1) At such times as the Secretary considers appropriate, the Secretary shall transmit to the Congress a report, based on the information provided under subsection (a), respecting—

“(A) a summary of research activities and proposed research activities on the health effects of ingredients added to tobacco in the manufacture of cigarettes and the findings of such research;

“(B) information pertaining to any such ingredient which in the judgment of the Secretary poses a health risk to cigarette smokers; and

“(C) any other information which the Secretary determines to be in the public interest.

“(2)(A) Any information provided to the Secretary under subsection (a) shall be treated as trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code and section 1905 of title 18, United States Code and shall not be revealed, except as provided in paragraph (1), to any person other than those

authorized by the Secretary in carrying out their official duties under this section.

“(B) Subparagraph (A) does not authorize the withholding of a list provided under subsection (a) from any duly authorized subcommittee or committee of the Congress. If a subcommittee or committee of the Congress requests the Secretary to provide it such a list, the Secretary shall make the list available to the subcommittee or committee and shall, at the same time, notify in writing the person who provided the list of such request.

“(C) The Secretary shall establish written procedures to assure the confidentiality of information provided under subsection (a). Such procedures shall include the designation of a duly authorized agent to serve as custodian of such information. The agent—

“(i) shall take physical possession of the information and, when not in use by a person authorized to have access to such information, shall store it in a locked cabinet or file, and

“(ii) shall maintain a complete record of any person who inspects or uses the information.

Such procedures shall require that any person permitted access to the information shall be instructed in writing not to disclose the information to anyone who is not entitled to have access to the information.”.

(b) Section 7 of the Federal Cigarette Labeling and Advertising Act added by subsection (a) shall take effect upon the expiration of the one-year period beginning on the date of the enactment of this Act.

MISCELLANEOUS AMENDMENTS

SEC. 6 (a) Paragraph (1) of section 2 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1331) is amended to read as follows:

“(1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and”.

(b) Section 3 of such Act (15 U.S.C. 1332) is amended by adding at the end of the following:

“(8) The term ‘Secretary’ means the Secretary of Health and Human Services.”.

(c) Section 8 of such Act (15 U.S.C. 1336) (as so redesignated) is amended to read as follows:

“FEDERAL TRADE COMMISSION

“SEC. 8. Nothing in this Act (other than the requirements of section 4(b)) shall be construed to limit, restrict, expand, or otherwise affect the authority of the Federal Trade Commission with respect to unfair or deceptive acts or practices in the advertising of cigarettes.”.

(d) Section 9 of such Act (15 U.S.C. 1337) (as so redesignated) is amended—

(1) by striking out “of Health, Education, and Welfare” in subsection (a),

(2) by redesignating clauses (A) and (B) in such subsection as clauses (1) and (2), respectively,

(3) by striking out clause (A) in subsection (b) and by redesignating clauses (B) and (C) as clauses (1) and (2), respectively.

Approved October 12, 1984.

Public Law 99-252
99th Congress

An Act

To provide for public education concerning the health consequences of using smokeless tobacco products.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Comprehensive Smokeless Tobacco Health Education Act of 1986".

SEC. 2. PUBLIC EDUCATION.

(a) DEVELOPMENT.—(1) The Secretary of Health and Human Services shall establish and carry out a program to inform the public of any dangers to human health resulting from the use of smokeless tobacco products. In carrying out such program the Secretary shall—

(A) develop educational programs and materials and public service announcements respecting the dangers to human health from the use of smokeless tobacco;

(B) make such programs, materials, and announcements available to States, local governments, school systems, the media, and such other entities as the Secretary determines appropriate to further the purposes of this Act;

(C) conduct and support research on the effect of smokeless tobacco on human health; and

(D) collect, analyze, and disseminate information and studies on smokeless tobacco and health.

(2) In developing programs, materials, and announcements under paragraph (1) the Secretary shall consult

with the Secretary of Education, medical and public health entities, consumer groups, representatives of manufacturers of smokeless tobacco products, and other appropriate entities.

(b) ASSISTANCE.—The Secretary of Health and Human Services may provide technical assistance and may make grants to States—

(1) to assist in the development of educational programs and materials and public service announcements respecting the dangers to human health from the use of smokeless tobacco,

(2) to assist in the distribution of such programs, materials, and announcements throughout the States, and

(3) to establish 18 as the minimum age for the purchase of smokeless tobacco.

SEC. 3. SMOKELESS TOBACCO WARNING.

(a) GENERAL RULE.—

(1) It shall be unlawful for any person to manufacture, package, or import for sale or distribution within the United States any smokeless tobacco product unless the product package bears, in accordance with the requirements of this Act, one of the following labels:

"WARNING: THIS PRODUCT MAY CAUSE MOUTH CANCER

"WARNING: THIS PRODUCT MAY CAUSE GUM DISEASE AND TOOTH LOSS

"WARNING: THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES".

(2) It shall be unlawful for any manufacturer, packager, or importer of smokeless tobacco prod-

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ucts to advertise or cause to be advertised (other than through the use of outdoor billboard advertising) within the United States any smokeless tobacco product unless the advertising bears, in accordance with the requirements of this Act, one of the labels required by paragraph (1).

(b) **LABEL FORMAT.**—The Federal Trade Commission shall issue regulations requiring the label statement required by subsection (a) to appear—

(1) in the case of the smokeless tobacco product package—

(A) in a conspicuous and prominent place on the package, and

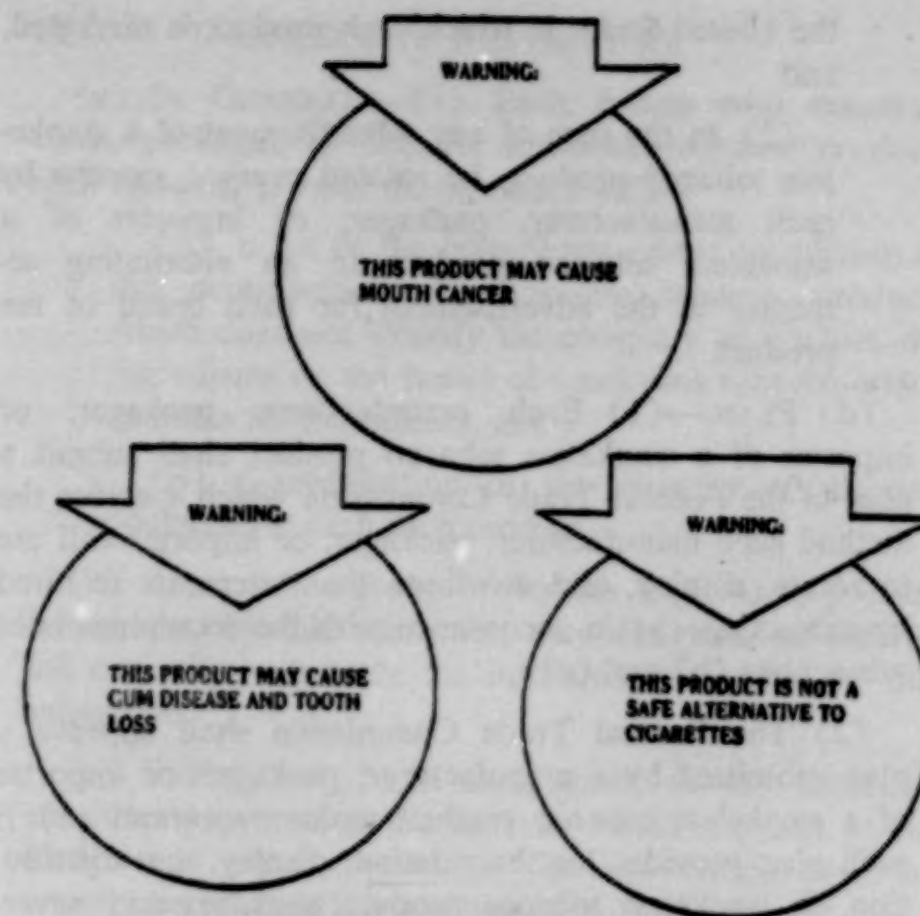
(B) in a conspicuous format and in conspicuous and legible type in contrast with all other printed material on the package, and

(2) in the case of advertising subject to subsection (a)(2)—

(A) in a conspicuous and prominent location in the advertisement and in conspicuous and legible type in contrast with all other printed material in the advertisement,

(B) in the following format:

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(C) the label statement shall appear in capital letters and the area of the circle and arrow shall be determined by the Federal Trade Commission.

(c) **LABEL DISPLAY.**—The Federal Trade Commission shall issue regulations requiring each label statement required by subsection (a) to—

(1) in the case of a smokeless tobacco product package, be randomly displayed by each manufacturer, packager, or importer of a smokeless tobacco product in each 12-month period in as equal a number of times as is possible on each brand of the product and be randomly distributed in all parts of

the United States in which such product is marketed, and

(2) in the case of any advertisement of a smokeless tobacco product, be rotated every 4 months by each manufacturer, packager, or importer of a smokeless tobacco product in an alternating sequence in the advertisement for each brand of the product.

(d) **PLAN.**—(1) Each manufacturer, packager, or importer of a smokeless tobacco product shall submit a plan to the Federal Trade Commission which specifies the method such manufacturer, packager, or importer will use to rotate, display, and distribute the statements required by subsection (a) in accordance with the requirements of subsections (b) and (c).

(2) The Federal Trade Commission shall approve a plan submitted by a manufacturer, packager, or importer of a smokeless tobacco product under paragraph (1) if such plan provides for the rotation, display, and distribution on smokeless tobacco product packages and advertisements of the statements required by subsection (a) in a manner which complies with this section and the regulations promulgated pursuant to this section.

(e) **APPLICATION.**—This section does not apply to a distributor or a retailer of any smokeless tobacco product which does not manufacture, package, or import smokeless tobacco products for sale or distribution within the United States.

(f) **TELEVISION AND RADIO ADVERTISING.**—Effective 6 months after the date of the enactment of this Act, it shall be unlawful to advertise smokeless tobacco on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.

SEC. 4. INGREDIENT REPORTING.

(a) **IN GENERAL.**—(1) Each person who manufactures, packages, or imports smokeless tobacco products shall annually provide the Secretary with—

(A) a list of the ingredients added to tobacco in the manufacture of smokeless tobacco products which does not identify the company which uses the ingredients or the brand of smokeless tobacco which contains the ingredients; and

(B) a specification of the quantity of nicotine contained in each such product.

(2) A person or group of persons required to provide information by this subsection may designate an individual or entity to provide the information required by this subsection.

(b) **REPORT.**—(1) At such times as the Secretary considers appropriate, the Secretary shall transmit to the Congress a report, based on the information provided under subsection (a), respecting—

(A) a summary of research activities and proposed research activities on the health effects of ingredients added to tobacco in the manufacture of smokeless tobacco products and the findings of such research;

(B) information pertaining to any such ingredient which in the judgment of the Secretary poses a health risk to users of smokeless tobacco; and

(C) any other information which the Secretary determines to be in the public interest.

(2)(A) Any information provided to the Secretary under subsection (a) shall be treated as a trade secret or confidential information subject to section 552(b)(4) of

title 5, United States Code, and shall not be revealed, except as provided in paragraph (1), to any person other than those authorized by the Secretary in carrying out their official duties under this section.

(B) Subparagraph (A) does not authorize the withholding of information provided under subsection (a) of this section from any duly authorized subcommittee or committee of the Congress. If a subcommittee or committee of the Congress requests the Secretary to provide it such information, the Secretary shall make the information available to the subcommittee or committee and shall, at the same time, notify in writing the person who provided the information of such request.

(C) The Secretary shall establish written procedures to assure the confidentiality of information provided under subsection (a) of this section. Such procedures shall include the designation of a duly authorized agent to serve as custodian of such information. The agent—

(i) shall take physical possession of the information and, when not in use by any person authorized to have access to such information, shall store it in a locked cabinet or file; and

(ii) shall maintain a complete record of any person who inspects or uses the information.

Such procedures shall require that any person permitted access to the information shall be instructed in writing not to disclose the information to anyone who is not entitled to have access to the information.

SEC. 5. ENFORCEMENT, REGULATIONS, AND CONSTRUCTION.

(a) ENFORCEMENT.—(1) A violation of section 3 or the regulations promulgated pursuant to this Act shall be

considered a violation of section 5 of the Federal Trade Commission Act.

(2) Any person who is found to violate any provision of section 3 or 4(a) shall be guilty of a misdemeanor and shall on conviction thereof be subject to a fine of not more than \$10,000.

(b) REGULATIONS UNDER SECTION 3.—(1) Regulations issued by the Federal Trade Commission under section 3 shall be issued in accordance with section 553 of title 5, United States Code.

(2) Not later than 180 days after the date of the enactment of this Act, the Federal Trade Commission shall promulgate such regulations as it may require to implement section 3.

(c) CONSTRUCTION.—Nothing in this Act (other than the requirements of sections 3 and 4) shall be construed to limit, restrict, or expand the authority of the Federal Trade Commission with respect to unfair or deceptive acts or practices in the advertising of smokeless tobacco products.

SEC. 6. INJUNCTIONS.

The several district courts of the United States are vested with jurisdiction, for cause shown, to prevent and restrain violations of sections 3 and 4 upon application of the Federal Trade Commission in the case of a violation of section 3 or upon application of the Attorney General of the United States acting through the several United States attorneys in their several districts in the case of a violation of section 3 or 4.

SEC. 7. PREEMPTION.

(a) **FEDERAL ACTION.**—No statement relating to the use of smokeless tobacco products and health, other than the statements required by section 3, shall be required by any Federal agency to appear on any package or in any advertisement (unless the advertisement is an outdoor billboard advertisement) of a smokeless tobacco product.

(b) **STATE AND LOCAL ACTION.**—No statement relating to the use of smokeless tobacco products and health, other than the statements required by section 3, shall be required by any State or local statute or regulation to be included on any package or in any advertisement (unless the advertisement is an outdoor billboard advertisement) of a smokeless tobacco product.

(c) **EFFECT ON LIABILITY LAW.**—Nothing in this Act shall relieve any person from liability at common law or under State statutory law to any other person.

SEC. 8. REPORTS.

(a) **SECRETARY'S REPORT.**—The Secretary of Health and Human Services shall transmit a report to the Congress not later than January 11, 1987, and biennially thereafter, containing—

(1) a description of the effects of health education efforts on the use of smokeless tobacco products,

(2) a description of the use by the public of smokeless tobacco products,

(3) an evaluation of the health effects of smokeless tobacco products and the identification of areas appropriate for further research, and

(4) such recommendations for legislation and administrative action as the Secretary considers appropriate.

(b) **FTC REPORT.**—The Federal Trade Commission shall transmit a report to the Congress not later than January 11, 1987, and biennially thereafter, containing (1) a description of the current sales, advertising, and marketing practices associated with smokeless tobacco products, and (2) such recommendations for legislation and administrative action as it deems appropriate.

SEC. 9. DEFINITIONS.

For purposes of this Act:

(1) The term “smokeless tobacco” means any finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral cavity.

(2) The term “commerce” means (A) commerce between any state, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island and any place outside thereof; (B) commerce between points in any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island, but through any place outside thereof; or (C) commerce wholly within the District of Columbia, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island.

(3) The term “United States”, when used in a geographical sense, includes the several States, the District of Columbia, the Commonwealth of Puerto Rico,

Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Island, and installations of the Armed Forces.

(4) The term "package" means a pack, box, carton, pouch, or container of any kind in which smokeless tobacco products are offered for sale, sold, or otherwise distributed to consumers.

(5) The term "sale or distribution" includes sampling or any other distribution not for sale.

(6) The term "Secretary" means the Secretary of Health and Human Services.

SEC. 10. TECHNICAL AMENDMENT.

Section 402(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(d)(2)) is amended by inserting before the semicolon a comma and the following: "except that this clause shall not apply to confectionery which is introduced or delivered for introduction into, or received or held for sale in, interstate commerce if the sale of such confectionery is permitted under the laws of the State in which such confectionery is intended to be offered for sale".

SEC. 11. EFFECTIVE DATE.

(a) IN GENERAL.—Except as provided in sections 3(f) and 5(b) and subsection (b), this Act shall take effect one year after the date of enactment of this Act.

(b) EXCEPTION.—Sections 2, 3(b), 3(c), 3(d), 3(e), 4(b), 7, 8, 9, and 10 shall take effect on the date of the enactment of this Act.

Approved February 27, 1986.

Public Law 102-321
102d Congress

An Act

To amend the Public Health Service Act to restructure the Alcohol, Drug Abuse, and Mental Health Administration and the authorities of such Administration, including establishing separate block grants to enhance the delivery of services regarding substance abuse and mental health, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

* * * *

TITLE II—BLOCK GRANTS TO STATES REGARDING MENTAL HEALTH AND SUBSTANCE ABUSE

* * * *

SEC. 202. ESTABLISHMENT OF SEPARATE BLOCK GRANT REGARDING SUBSTANCE ABUSE.

Part B of title XIX of the Public Health Service Act, as amended by section 201 of this Act, is amended by adding at the end the following:

"Subpart II—Block Grants for Prevention and Treatment of Substance Abuse

* * * *

"SEC. 1926. STATE LAW REGARDING SALE OF TOBACCO PRODUCTS TO INDIVIDUALS UNDER AGE OF 18.

"(a) RELEVANT LAW.—

"(1) IN GENERAL.—Subject to paragraph (2), for fiscal year 1994 and subsequent fiscal years, the

Secretary may make a grant under section 1921 only if the State involved has in effect a law providing that it is unlawful for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under the age of 18.

“(2) **DELAYED APPLICABILITY FOR CERTAIN STATES.**—In the case of a State whose legislature does not convene a regular session in fiscal year 1993, and in the case of a State whose legislature does not convene a regular session in fiscal year 1994, the requirement described in paragraph (1) as a condition of a receipt of a grant under section 1921 shall apply only for fiscal year 1995 and subsequent fiscal years.

“(b) **ENFORCEMENT.**—

“(1) **IN GENERAL.**—For the first applicable fiscal year and for subsequent fiscal years, a funding agreement for a grant under section 1921 is that the State involved will enforce the law described in subsection (a) in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18.

“(2) **ACTIVITIES AND REPORTS REGARDING ENFORCEMENT.**—For the first applicable fiscal year and for subsequent fiscal years, a funding agreement for a grant under section 1921 is that the State involved will—

“(A) annually conduct random, unannounced inspections to ensure compliance with the law described in subsection (a); and

“(B) annually submit to the Secretary a report describing—

“(i) the activities carried out by the State to enforce such law during the fiscal year preceding the fiscal year for which the State is seeking the grant;

“(ii) the extent of success the State has achieved in reducing the availability of tobacco products to individuals under the age of 18; and

“(iii) the strategies to be utilized by the State for enforcing such law during the fiscal year for which the grant is sought.

“(c) **NONCOMPLIANCE OF STATE.**—Before making a grant under section 1921 to a State for the first applicable fiscal year or any subsequent fiscal year, the Secretary shall make a determination of whether the State has maintained compliance with subsections (a) and (b). If, after notice to the State and an opportunity for a hearing, the Secretary determines that the State is not in compliance with such subsections, the Secretary shall reduce the amount of the allotment under such section for the State for the fiscal year involved by an amount equal to—

“(1) in the case of the first applicable fiscal year, 10 percent of the amount determined under section 1933 for the State for the fiscal year;

“(2) in the case of the first fiscal year following such applicable fiscal year, 20 percent of the amount determined under section 1933 for the State for the fiscal year;

“(3) in the case of the second such fiscal year, 30 percent of the amount determined under section 1933 for the State for the fiscal year; and

“(4) in the case of the third such fiscal year or any subsequent fiscal year, 40 percent of the amount

determined under section 1933 for the State for the fiscal year.

“(d) DEFINITION.—For purposes of this section, the term ‘first applicable fiscal year’ means—

“(1) fiscal year 1995, in the case of any State described in subsection (a)(2); and

“(2) fiscal year 1994, in the case of any other State.

UNITED STATES CODE
TITLE 15. COMMERCE AND TRADE
CHAPTER 36—CIGARETTE LABELING AND
ADVERTISING

Sec. 1331. Congressional declaration of policy and purpose

It is the policy of the Congress, and the purpose of this chapter, to establish a comprehensive Federal Program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby—

(1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and

(2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.

Sec. 1332. Definitions

As used in this chapter—

(1) The term “cigarette” means—

(A) any roll of tobacco wrapped in paper or in any substance not containing tobacco, and

(B) any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in subparagraph (A).

(2) The term "commerce" means (A) commerce between any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island and any place outside thereof; (B) commerce between points in any state, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island, but through any place outside thereof; or (C) commerce wholly within the District of Columbia, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island.

(3) The term "United States", when used in a geographical sense, includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, and Johnston Island. The term "State" includes any political division of any State.

(4) The term "package" means a pack, box, carton, or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers.

(5) The term "person" means an individual, partnership, corporation, or any other business or legal entity.

(6) The term "sale or distribution" includes sampling or any other distribution not for sale.

(7) The term "little cigar" means any roll of tobacco wrapped in leaf tobacco or any substance containing tobacco (other than any roll of tobacco which is a cigarette within the meaning of subsection (1) of this section) and as to which one thousand units weigh not more than three pounds.

(8) The term "brand style" means a variety of cigarettes distinguished by the tobacco used, tar and nicotine content, flavoring used, size of the cigarette, filtration on the cigarette, or packaging.

(9) The term "Secretary" means the Secretary of Health and Human Services.

Sec. 1333. Labeling; requirements; conspicuous statement

(a) Required warnings; packages; advertisement; billboards

(1) It shall be unlawful for any person to manufacture, package, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:

SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.

SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.

SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.

SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

(2) It shall be unlawful for any manufacturer or importer of cigarettes to advertise or cause to be advertised (other than through the use of outdoor billboards) within the United States any cigarette unless the advertising bears,

in accordance with the requirements of this section, one of the following labels:

SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.

SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.

SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.

SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

(3) It shall be unlawful for any manufacturer or importer of cigarettes to advertise or cause to be advertised within the United States through the use of outdoor billboards any cigarette unless the advertising bears, in accordance with the requirements of this section, one of the following labels:

SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, and Emphysema.

SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Health Risks.

SURGEON GENERAL'S WARNING: Pregnant Women Who Smoke Risk Fetal Injury And Premature Birth.

SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

(b) Conspicuous statement; label statement format; outdoor billboard statement format

(1) Each label statement required by paragraph (1) of subsection (a) of this section shall be located in the place label statements were placed on cigarette packages as of October 12, 1984. The phrase "Surgeon General's Warning" shall appear in capital letters and the size of all other letters in the label shall be the same size of such letters as of October 12, 1984. All the letters in the label shall appear in conspicuous and legible type in contrast by typography, layout, or color with all other printed material on the package.

(2) The format of each label statement required by paragraph (2) of subsection (a) of this section shall be the format required for label statements in cigarette advertising as of October 12, 1984, except that the phrase "Surgeon General's Warning" shall appear in capital letters, the area of the rectangle enclosing the label shall be 50 per centum larger in size with a corresponding increase in size of the type in the label, the width of the rule forming the border around the label shall be twice that in effect on October 12, 1984, and the label may be placed at a distance from the outer edge of the advertisement which is one-half the distance permitted on October 12, 1984. Each label statement shall appear in conspicuous and legible type in contrast by typography, layout, or color with all other printed material in the advertisement.

(3) The format and type style of each label statement required by paragraph (3) of subsection (a) of this section shall be the format and type style required in outdoor billboard advertising as of October 12, 1984. Each such label statement shall be printed in capital letters of the height of the tallest letter in a label statement on outdoor advertising of the same dimension on October 12, 1984.

Each such label statement shall be enclosed by a black border which is located within the perimeter of the format required in outdoor billboard advertising of the same dimension on October 12, 1984, and the width of which is twice the width of the vertical element of any letter in the statement within the border.

(c) Rotation of label statement; plan; submission to Federal Trade Commission

(1) Except as provided in paragraph (2), the label statements specified in paragraphs (1), (2), and (3) of subsection (a) of this section shall be rotated by each manufacturer or importer of cigarettes quarterly in alternating sequence on packages of each brand of cigarettes manufactured by the manufacturer or importer and in the advertisements for each such brand of cigarettes in accordance with a plan submitted by the manufacturer or importer and approved by the Federal Trade Commission. The Federal Trade Commission shall approve a plan submitted by a manufacturer or importer of cigarettes which will provide the rotation required by this subsection and which assures that all of the labels required by paragraphs (1), (2), and (3) will be displayed by the manufacturer or importer at the same time.

(2)(A) A manufacturer or importer of cigarettes may apply to the Federal Trade Commission to have the label rotation described in subparagraph (C) apply with respect to a brand style of cigarettes manufactured or imported by such manufacturer or importer if—

(i) the number of cigarettes of such brand style sold in the fiscal year of the manufacturer or importer preceding the submission of the application is less than one-fourth of 1 percent of all the cigarettes sold in the United States in such year, and

(ii) more than one-half of the cigarettes manufactured or imported by such manufacturer or importer for sale in the United States are packaged into brand styles which meet the requirements of clause (i).

If an application is approved by the Commission, the label rotation described in subparagraph (C) shall apply with respect to the applicant during the one year period beginning on the date of the application approval.

(B) An applicant under subparagraph (A) shall include in its application a plan under which the label statements specified in paragraph (1) of subsection (a) of this section will be rotated by the applicant manufacturer or importer in accordance with the label rotation described in subparagraph (C).

(C) Under the label rotation which a manufacturer or importer with an approved application may put into effect each of the labels specified in paragraph (1) of subsection (a) of this section shall appear on the packages of each brand style of cigarettes with respect to which the application was approved an equal number of times within the twelve-month period beginning on the date of the approval by the Commission of the application.

(d) Application; distributors; retailers

Subsection (a) of this section does not apply to a distributor or a retailer of cigarettes who does not manufacture, package, or import cigarettes for sale or distribution within the United States.

Sec. 1334. Preemption

(a) Additional statements

No statement relating to smoking and health, other than the statements required by section 1333 of this title, shall be required on any cigarette package.

(b) State regulations

No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.

Sec. 1335. Unlawful advertisements on medium of electronic communication

After January 1, 1971, it shall be unlawful to advertise cigarettes and little cigars on any medium of electronic communication subject to the jurisdiction of the Federal Communications Commission.

Sec. 1335a. List of cigarette ingredients; annual submission to Secretary; transmittal to Congress; confidentiality

(a) Each person who manufactures, packages, or imports cigarettes shall annually provide the Secretary with a list of the ingredients added to tobacco in the manufacture of cigarettes which does not identify the company which uses the ingredients or the brand of cigarettes which contain the ingredients. A person or group of persons required to provide a list by this subsection may designate an individual or entity to provide the list required by this subsection.

(b)(1) At such times as the Secretary considers appropriate, the Secretary shall transmit to the Congress a report, based on the information provided under subsection (a) of this section, respecting—

(A) a summary of research activities and proposed research activities on the health effects of in-

gredients added to tobacco in the manufacture of cigarettes and the findings of such research;

(B) information pertaining to any such ingredient which in the judgement¹ of the Secretary poses a health risk to cigarette smokers; and

(C) any other information which the Secretary determines to be in the public interest.

(2)(A) Any information provided to the Secretary under subsection (a) of this section shall be treated as trade secret or confidential information subject to section 552(b)(4) of title 5 and section 1905 of title 18 and shall not be revealed, except as provided in paragraph (1), to any person other than those authorized by the Secretary in carrying out their official duties under this section.

(B) Subparagraph (A) does not authorize the withholding of a list provided under subsection (a) of this section from any duly authorized subcommittee or committee of the Congress. If a subcommittee or committee of the Congress requests the Secretary to provide it such a list, the Secretary shall make the list available to the subcommittee or committee and shall, at the same time, notify in writing the person who provided the list of such request.

(C) The Secretary shall establish written procedures to assure the confidentiality of information provided under subsection (a) of this section. Such procedures shall include the designation of a duly authorized agent to serve as custodian of such information. The agent—

(i) shall take physical possession of the information and, when not in use by a person authorized to have access to such information, shall store it in a locked cabinet or file, and

¹ So in original. Probably should be "judgment".

(ii) shall maintain a complete record of any person who inspects or uses the information.

Such procedures shall require that any person permitted access to the information shall be instructed in writing not to disclose the information to anyone who is not entitled to have access to the information.

Sec. 1336. Authority of Federal Trade Commission; unfair or deceptive acts or practices

Nothing in this chapter (other than the requirements of section 1333 of this title) shall be construed to limit, restrict, expand, or otherwise affect the authority of the Federal Trade Commission with respect to unfair or deceptive acts or practices in the advertising of cigarettes.

Sec. 1337. Reports to Congress by the Secretary and Federal Trade Commission

(a) The Secretary shall transmit a report to the Congress not later than January 1, 1971, and annually thereafter, concerning (1) current information in the health consequences of smoking, and (2) such recommendations for legislation as he may deem appropriate.

(b) The Federal Trade Commission shall transmit a report to the Congress not later than January 1, 1971, and annually thereafter, concerning (1) current practices and methods of cigarette advertising and promotion, and (2) such recommendations for legislation as it may deem appropriate.

Sec. 1338. Criminal penalty

Any person who violates the provisions of this chapter shall be guilty of a misdemeanor and shall on conviction thereof be subject to a fine of not more than \$10,000.

Sec. 1339. Injunction proceedings

The several district courts of the United States are invested with jurisdiction, for cause shown, to prevent and restrain violations of this chapter upon the application of the Attorney General of the United States acting through the several United States attorneys in their several districts.

Sec. 1340. Cigarettes for export

Packages of cigarettes manufactured, imported, or packaged (1) for export from the United States or (2) for delivery to a vessel or aircraft, as supplies, for consumption beyond the jurisdiction of the internal revenue laws of the United States shall be exempt from the requirements of this chapter, but such exemptions shall not apply to cigarettes manufactured, imported, or packaged for sale or distribution to members or units of the Armed Forces of the United States located outside of the United States.

Sec. 1341. Smoking, research, education and information

(a) Establishment of program; Secretary; functions

The Secretary of Health and Human Services (hereinafter in this section referred to as the "Secretary") shall establish and carry out a program to inform the public of any dangers to human health presented by cigarette smoking. In carrying out such program, the Secretary shall—

(1) conduct and support research on the effect of cigarette smoking on human health and develop materials for informing the public of such effect;

(2) coordinate all research and educational programs and other activities within the Department of Health and Human Services (hereinafter in this section referred to as the "Department") which relate

to the effect of cigarette smoking on human health and coordinate, through the Interagency Committee on Smoking and Health (established under subsection (b) of this section), such activities with similar activities of other Federal agencies and of private agencies;

(3) establish and maintain a liaison with appropriate private entities, other Federal agencies, and State and local public agencies respecting activities relating to the effect of cigarette smoking on human health;

(4) collect, analyze, and disseminate (through publications, bibliographies, and otherwise) information, studies, and other data relating to the effect of cigarette smoking on human health, and develop standards, criteria, and methodologies for improved information programs related to smoking and health;

(5) compile and make available information on State and local laws relating to the use and consumption of cigarettes; and

(6) undertake any other additional information and research activities which the Secretary determines necessary and appropriate to carry out this section.

(b) Interagency Committee on Smoking and Health; composition; chairman; compensation; staffing and other assistance

(1) To carry out the activities described in paragraphs (2) and (3) of subsection (a) of this section there is established an Interagency Committee on Smoking and Health. The Committee shall be composed of—

(A) members appointed by the Secretary from appropriate institutes and agencies of the Depart-

ment, which may include the National Cancer Institute, the National Heart, Lung, and Blood Institute, the National Institute of Child Health and Human Development, the National Institute on Drug Abuse, the Health Resources and Services Administration, and the Centers for Disease Control and Prevention;

(B) at least one member appointed from the Federal Trade Commission, the Department of Education, the Department of Labor, and any other Federal agency designated by the Secretary, the appointment of whom shall be made by the head of the entity from which the member is appointed; and

(C) five members appointed by the Secretary from physicians and scientists who represent private entities involved in informing the public about the health effects of smoking.

The Secretary shall designate the chairman of the Committee.

(2) While away from their homes or regular places of business in the performance of services for the Committee, members of the Committee shall be allowed travel expenses, including per diem in lieu of subsistence,¹ in the manner provided by sections 5702 and 5703 of title 5.

(3) The Secretary shall make available to the Committee such staff, information, and other assistance as it may require to carry out its activities effectively.

(c) Report to Congress; contents

The Secretary shall transmit a report to Congress not later than January 1, 1986, and biennially thereafter which shall contain—

¹ So in original. Probably should be "subsistence,".

(1) an overview and assessment of Federal activities undertaken to inform the public of the health consequences of smoking and the extent of public knowledge of such consequences,

(2) a description of the Secretary's and Committee's activities under subsection (a) of this section,

(3) information regarding the activities of the private sector taken in response to the effects of smoking on health, and

(4) such recommendations as the Secretary may consider appropriate.

CHAPTER 70—COMPREHENSIVE SMOKELESS TOBACCO HEALTH EDUCATION

Sec. 4401. Public education

(a) Development

(1) The Secretary of Health and Human Services shall establish and carry out a program to inform the public of any dangers to human health resulting from the use of smokeless tobacco products. In carrying out such program the Secretary shall—

(A) develop educational programs and materials and public service announcements respecting the dangers to human health from the use of smokeless tobacco;

(B) make such programs, materials, and announcements available to States, local governments, school systems, the media, and such other entities as the Secretary determines appropriate to further the purposes of this chapter;

(C) conduct and support research on the effect of smokeless tobacco on human health; and

(D) collect, analyze, and disseminate information and studies on smokeless tobacco and health.

(2) In developing programs, materials, and announcements under paragraph (1)¹ the Secretary shall consult with the Secretary of Education, medical and public health entities, consumer groups, representatives of manufacturers of smokeless tobacco products, and other appropriate entities.

¹ So in original. Probably should be followed by a comma.

(b) Assistance

The Secretary of Health and Human Services may provide technical assistance and may make grants to States—

(1) to assist in the development of educational programs and materials and public service announcements respecting the dangers to human health from the use of smokeless tobacco,

(2) to assist in the distribution of such programs, materials, and announcements throughout the States, and

(3) to establish 18 as the minimum age for the purchase of smokeless tobacco.

Sec. 4402. Smokeless tobacco warning**(a) General rule**

(1) It shall be unlawful for any person to manufacture, package, or import for sale or distribution within the United States any smokeless tobacco product unless the product package bears, in accordance with the requirements of this chapter, one of the following labels:

“WARNING: THIS PRODUCT MAY CAUSE MOUTH CANCER

“WARNING: THIS PRODUCT MAY CAUSE GUM DISEASE AND TOOTH LOSS

“WARNING: THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES”.

(2) It shall be unlawful for any manufacturer, packager, or importer of smokeless tobacco products to advertise or cause to be advertised (other than through the use of outdoor billboard advertising) within the United States any smokeless tobacco product unless the advertising bears, in

accordance with the requirements of this chapter, one of the labels required by paragraph (1).

(b) Label format

The Federal Trade Commission shall issue regulations requiring the label statement required by subsection (a) of this section to appear—

(1) in the case of the smokeless tobacco product package—

(A) in a conspicuous and prominent place on the package, and

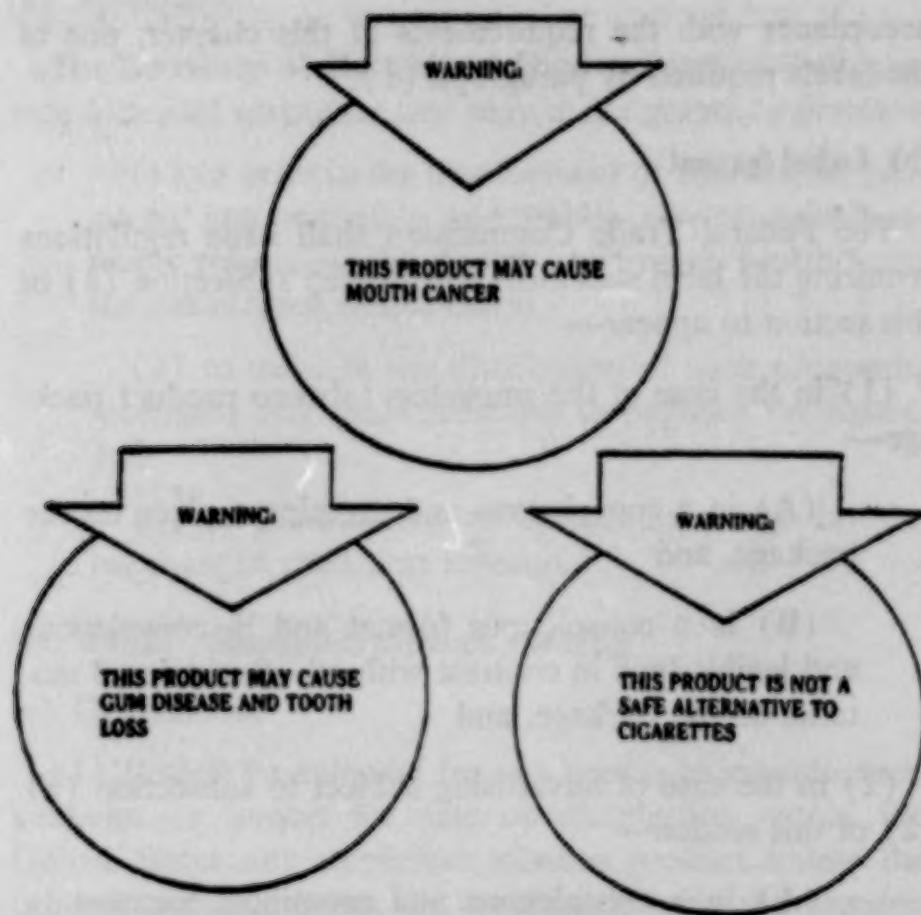
(B) in a conspicuous format and in conspicuous and legible type in contrast with all other printed material on the package, and

(2) in the case of advertising subject to subsection (a) (2) of this section—

(A) in a conspicuous and prominent location in the advertisement and in conspicuous and legible type in contrast with all other printed material in the advertisement,

(B) in the following format:

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(C) the label statement shall appear in capital letters and the area of the circle and arrow shall be determined by the Federal Trade Commission.

(c) Label display

The Federal Trade Commission shall issue regulations requiring each label statement required by subsection (a) of this section to—

(1) in the case of a smokeless tobacco product package, be randomly displayed by each manufacturer, packager, or importer of a smokeless tobacco product in each 12-month period in as equal a number of times as is possible on each brand of the prod-

73a

uct and be randomly distributed in all parts of the United States in which such product is marked, and

(2) in the case of any advertisement of a smokeless tobacco product, be rotated every 4 months by each manufacturer, packager, or importer of a smokeless tobacco product in an alternating sequence in the advertisement for each brand of the product.

(d) Plan

(1) Each manufacturer, packager, or importer of a smokeless tobacco product shall submit a plan to the Federal Trade Commission which specifies the method such manufacturer, packager, or importer will use to rotate, display, and distribute the statements required by subsection (a) of this section in accordance with the requirements of subsections (b) and (c) of this section.

(2) The Federal Trade Commission shall approve a plan submitted by a manufacturer, packager, or importer of a smokeless tobacco product under paragraph (1) if such plan provides for the rotation, display, and distribution on smokeless tobacco product packages and advertisements of the statements required by subsection (a) of this section in a manner which complies with this section and the regulations promulgated pursuant to this section.

(e) Application

This section does not apply to a distributor or a retailer of any smokeless tobacco product which does not manufacture, package, or import smokeless tobacco products for sale or distribution within the United States.

(f) Television and radio advertising

Effective 6 months after February 27, 1986, it shall be unlawful to advertise smokeless tobacco on any medium of

electronic communications subject to the jurisdiction of the Federal Communications Commission.

Sec. 4403. Ingredient reporting

(a) In general

(1) Each person who manufactures, packages, or imports smokeless tobacco products shall annually provide the Secretary with—

(A) a list of the ingredients added to tobacco in the manufacture of smokeless tobacco products which does not identify the company which uses the ingredients or the brand of smokeless tobacco which contains the ingredients; and

(B) a specification of the quantity of nicotine contained in each such product.

(2) A person or group of persons required to provide information by this subsection may designate an individual or entity to provide the information required by this subsection.

(b) Report

(1) At such times as the Secretary considers appropriate, the Secretary shall transmit to the Congress a report, based on the information provided under subsection (a) of this section, respecting—

(A) a summary of research activities and proposed research activities on the health effects of ingredients added to tobacco in the manufacture of smokeless tobacco products and the findings of such research;

(B) information pertaining to any such ingredient which in the judgment of the Secretary poses a health risk to users of smokeless tobacco; and

(C) any other information which the Secretary determines to be in the public interest.

(2)(A) Any information provided to the Secretary under subsection (a) of this section shall be treated as a trade secret or confidential information subject to section 552(b)(4) of title 5 and shall not be revealed, except as provided in paragraph (1), to any person other than those authorized by the Secretary in carrying out their official duties under this section.

(B) Subparagraph (A) does not authorize the withholding of information provided under subsection (a) of this section from any duly authorized subcommittee or committee of the Congress. If a subcommittee or committee of the Congress requests the Secretary to provide such information, the Secretary shall make the information available to the subcommittee or committee and shall, at the same time, notify in writing the person who provided the information of such request.

(C) The Secretary shall establish written procedures to assure the confidentiality of information provided under subsection (a) of this section. Such procedures shall include the designation of a duly authorized agent to serve as custodian of such information. The agent—

(i) shall take physical possession of the information and, when not in use by any person authorized to have access to such information, shall store it in a locked cabinet or file; and

(ii) shall maintain a complete record of any person who inspects or uses the information.

Such procedures shall require that any person permitted access to the information shall be instructed in writing not to disclose the information to anyone who is not entitled to have access to the information.

Sec. 4404. Enforcement, regulation, and construction**(a) Enforcement**

(1) A violation of section 4402 of this title or the regulations promulgated pursuant to this chapter shall be considered a violation of section 45 of this title.

(2) Any person who is found to violate any provision of section 4402 or 4403(a) of this title shall be guilty of a misdemeanor and shall on conviction thereof be subject to a fine of not more than \$10,000.

(b) Regulations under section 4402 of this title

(1) Regulations issued by the Federal Trade Commission under section 4402 of this title shall be issued in accordance with section 553 of title 5.

(2) Not later than 180 days after February 27, 1986, the Federal Trade Commission shall promulgate such regulations as it may require to implement section 4402 of this title.

(c) Construction

Nothing in this chapter (other than the requirements of sections 4402 and 4403 of this title) shall be construed to limit, restrict, or expand the authority of the Federal Trade Commission with respect to unfair or deceptive acts or practices in the advertising of smokeless tobacco products.

Sec. 4405. Injunctions

The several district courts of the United States are vested with jurisdiction, for cause shown, to prevent and restrain violations of sections 4402 and 4403 of this title upon application of the Federal Trade Commission in the case of a violation of section 4402 of this title, or upon application of the Attorney General of the United States acting through the several United States attorneys in their

several districts in the case of a violation of section 4402 or 4403 of this title.

Sec. 4406. Preemption**(a) Federal action**

No statement relating to the use of smokeless tobacco products and health, other than the statements required by section 4402 of this title, shall be required by any Federal agency to appear on any package or in any advertisement (unless the advertisement is an outdoor billboard advertisement) of a smokeless tobacco product.

(b) State and local action

No statement relating to the use of smokeless tobacco products and health, other than the statements required by section 4402 of this title, shall be required by any State or local statute or regulation to be included on any package or in any advertisement (unless the advertisement is an outdoor billboard advertisement) of a smokeless tobacco product.

(c) Effect on liability law

Nothing in this chapter shall relieve any person from liability at common law or under State statutory law to any other person.

Sec. 4407. Reports**(a) Secretary's report**

The Secretary of Health and Human Services, shall transmit a report to the Congress not later than January 11, 1987, and biennially thereafter, containing—

(1) a description of the effects of health education efforts on the use of smokeless tobacco products,

(2) a description of the use by the public of smokeless tobacco products,

(3) an evaluation of the health effects of smokeless tobacco products and the identification of areas appropriate for further research, and

(4) such recommendations for legislation and administrative action as the Secretary considers appropriate.

(b) FTC report

The Federal Trade Commission shall transmit a report to the Congress not later than January 11, 1987, and biennially thereafter, containing (1) a description of the current sales, advertising, and marketing practices associated with smokeless tobacco products, and (2) such recommendations for legislation and administrative action as it deems appropriate.

Sec. 4408. Definitions

For purposes of this chapter:

(1) The term "smokeless tobacco" means any finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral cavity.

(2) The term "commerce" means (A) commerce between any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island and any place outside thereof; (B) commerce between points in any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island, but through any place outside thereof; or (C) commerce wholly within the District of Columbia, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island.

(3) The term "United States", when used in a geographical sense, includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Island, and installations of the Armed Forces.

(4) The term "package" means a pack, box, carton, pouch, or container of any kind in which smokeless tobacco products are offered for sale, sold, or otherwise distributed to consumers.

(5) The term "sale or distribution" includes sampling or any other distribution not for sale.

(6) The term "Secretary" means the Secretary of Health and Human Services.

TITLE 20. EDUCATION
CHAPTER 68—NATIONAL EDUCATION REFORM
SUBCHAPTER X—MISCELLANEOUS
PART B—ENVIRONMENTAL TOBACCO SMOKE

Sec. 6083. Nonsmoking policy for children's services

(a) Prohibition

After March 31, 1994, no person shall permit smoking within any indoor facility owned or leased or contracted for and utilized by such person for provision of routine or regular kindergarten, elementary, or secondary education or library services to children.

(b) Additional prohibition

After March 31, 1994, no person shall permit smoking within any indoor facility (or portion thereof) owned or leased or contracted for by such person for the provision by such person of regular or routine health care or day care or early childhood development (Head Start) services to children or for the use of the employees of such person who provides such services, except that this subsection shall not apply to—

(1) any portion of such facility that is used for inpatient hospital treatment of individuals dependent on, or addicted to, drugs or alcohol; and

(2) any private residence.

(c) Federal agencies

(1) Kindergarten, elementary, or secondary education or library services

After March 31, 1994, no Federal agency shall permit smoking within any indoor facility in the United

States operated by such agency, directly or by contract, to provide routine or regular kindergarten, elementary, or secondary education or library services to children.

(2) Health or day care or early childhood development services

After March 31, 1994, no Federal agency shall permit smoking within any indoor facility (or portion thereof) operated by such agency, directly or by contract, to provide routine or regular health or day care or early childhood development (Head Start) services to children, except that this paragraph shall not apply to—

(A) any portion of such facility that is used for inpatient hospital treatment of individuals dependent on, or addicted to, drugs or alcohol; and

(B) any private residence.

(3) Application of provisions

The provisions of paragraph (2) shall also apply to the provision of such routine or regular kindergarten, elementary or secondary education or library services in the facilities described in paragraph (2) not subject to paragraph (1).

(d) Notice

The prohibitions in subsections (a) through (c) of this section shall be incorporated by publication of a notice in the Federal Register by the Secretary (in consultation with the heads of other affected agencies) and by such agency heads in funding arrangements involving the provision of children's services administered by such heads. Such prohibitions shall be effective 90 days after such

notice is published, or 270 days after March 31, 1994, whichever occurs first.

(e) Special waiver

(1) In general

On receipt of an application, the head of the Federal agency may grant a special waiver to a person described in subsection (a) of this section who employs individuals who are members of a labor organization and provide children's services pursuant to a collective bargaining agreement that—

(A) took effect before March 31, 1994; and

(B) includes provisions relating to smoking privileges that are in violation of the requirements of this section.

(2) Termination of waiver

A special waiver granted under this subsection shall terminate on the earlier of—

(A) the first expiration date (after March 31, 1994) of the collective bargaining agreement containing the provisions relating to smoking privileges; or

(B) the date that is 1 year after March 31, 1994.

(f) Civil penalties

(1) In general

Any failure to comply with a prohibition in this section shall be a violation of this section and any person subject to such prohibition who commits such violation may be liable to the United States for a civil

penalty in an amount not to exceed \$1,000 for each violation, or may be subject to an administrative compliance order, or both, as determined by the Secretary. Each day a violation continues shall constitute a separate violation. In the case of any civil penalty under this section, the total amount shall not exceed the amount of Federal funds received by such person for the fiscal year in which the continuing violations occurred. For the purpose of the prohibition in subsection (c) of this section, the term "person" shall mean the head of the applicable Federal agency or the contractor of such agency providing the services to children.

(2) Administrative proceeding

A civil penalty may be assessed in a written notice, or an administrative compliance order may be issued, by the Secretary only after an opportunity for a hearing in accordance with section 554 of title 5. Before making such assessment or issuing such order, or both, the Secretary shall give written notice thereof to such person by certified mail with return receipt and provide therein an opportunity to request in writing not later than 30 days after the date of receipt of such notice such hearing. The notice shall reasonably describe the violation and be accompanied with the procedures for such hearing and a simple form to request such hearing if such person desires to use such form. If a hearing is requested, the Secretary shall establish by such certified notice the time and place for such hearing which should be located, to the greatest extent possible, at a location convenient to such person. The Secretary (or the Secretary's designee) and such person may consult to

arrange a suitable date and location where appropriate.

(3) Circumstances affecting penalty or order

In determining the amount of the civil penalty or the nature of the administrative compliance order, the Secretary shall take into account, as appropriate—

(A) the nature, circumstances, extent, and gravity of the violation;

(B) with respect to the violator, any good faith efforts to comply, the importance of achieving early and permanent compliance, the ability to pay or comply, the effect of the penalty or order on the ability to continue operation, any prior history of the same kind of violation, the degree of culpability, and any demonstration of willingness to comply with the prohibitions of this section in a timely manner; and

(C) such other matters as justice may require.

(4) Modification

The Secretary may, as appropriate, compromise, modify, or remit, with or without conditions, any civil penalty or administrative compliance order. In the case of a civil penalty, the amount, as finally determined by the Secretary or agreed upon in compromise, may be deducted from any sums that the United States or its agencies or instrumentalities owes to the person against whom the penalty is assessed.

(5) Petition for review

Any person aggrieved by a penalty assessed or an order issued, or both, by the Secretary under this section may file a petition for judicial review thereof with

the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which the person resides or transacts business. Such person shall provide a copy thereof to the Secretary or the Secretary's designee. The petition shall be filed within 30 days after the Secretary's assessment or order, or both, are final and have been provided to such person by certified mail. The Secretary shall promptly provide to the court a certified copy of the transcript of any hearing held under this section and a copy of the notice or order.

(6) Failure to comply

If a person fails to pay an assessment of a civil penalty or comply with an order, after either or both are final under this section, or after a court under paragraph (5) has entered a final judgment in favor of the Secretary, the Attorney General, at the request of the Secretary, shall recover the amount of the civil penalty (plus interest at then currently prevailing rates from the day either or both are final) or enforce the order in an action brought in the appropriate district court of the United States. In such action, the validity and appropriateness of the penalty or order or the amount of the penalty shall not be subject to review.

TITLE 21—FOOD AND DRUGS
CHAPTER 9—FEDERAL FOOD, DRUG,
AND COSMETIC ACT
SUBCHAPTER V—DRUGS AND DEVICES

Sec. 321. Definitions; generally

For the purposes of this chapter—

* * * *

(f) The term “food” means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g)(1) The term “drug” means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph. A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.

* * * *

(h) The term “device” (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

(2) intended for use in the diagnosis of diseases or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

* * * *

(ff) The term “dietary supplement”—

(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(A) a vitamin;

(B) a mineral;

(C) an herb or other botanical;

(D) an amino acid;

(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

(2) means a product that—

(A)(i) is intended for ingestion in a form described in section 350(c)(1)(B)(i) of this title; or

(ii) complies with section 350(c)(1)(B)(ii) of this title;

(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

(C) is labeled as a dietary supplement; and
(3) does—

(A) include an article that is approved as a new drug under section 355 of this title or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262) and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 342(f) of this title; and

(B) not include—

(i) an article that is approved as a new drug under section 355 of this title, certified as an antibiotic under section 357 of

this title, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262), or

(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,

which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter.

Except for purposes of subsection (g) of this section, a dietary supplement shall be deemed to be a food within the meaning of this chapter.

SUBCHAPTER III—PROHIBITED ACTS AND PENALTIES

Sec. 331. Prohibited acts

The following acts and the causing thereof are prohibited:

* * * *

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

* * * *

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a food, drug, device, or cosmetic, if such act is done

while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

* * * *

SUBCHAPTER V—DRUGS AND DEVICES

Sec. 352. Misbranded drugs and devices

A drug or device shall be deemed to be misbranded—

* * * *

(f) Directions for use and warnings on label

Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

* * * *

(j) Health-endangering when used as prescribed

If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

* * * *

Sec. 355. New drugs

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

(b) Filing application; contents

(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (F) specimens of the labeling proposed to be used for such drug. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date

but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences. The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A).

(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c) of this section—

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of

the new drug for which the application is submitted; and

(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

(3)(A) An applicant who makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give the notice required by subparagraph (B) to—

(i) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

(ii) the holder of the approved applicant under subsection (b) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

(B) The notice referred to in subparagraph (A) shall state that an application has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

(C) If an application is amended to include a certification described in paragraph (2)(A)(iv), the notice

required by subparagraph (B) shall be given when the amended application is submitted.

(4)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or under section 351 of the Public Health Service Act [42 U.S.C. 262], which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 262 of title 42 if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an effectiveness claim. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.

(C) Any agreement regarding the parameters of the design and size of clinical trials of a new drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the review-

ing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection or section 351 of the Public Health Service Act [42 U.S.C. 262] (including all scientific and medical matters, chemistry, manufacturing, and controls).

* * * *

(d) Grounds for refusing application; approval of application; "substantial evidence" defined

If the Secretary finds, after due notice to the applicant in accordance with subsection (c) of this section and giv-

ing him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b) of this section, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b) of this section; or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e) of this section, the term "substantial evidence" means evidence consisting of

adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence.

* * * *

Sec. 360e. Premarket approval

(a) General requirement

A class III device—

(1) which is subject to a regulation promulgated under subsection (b) of this section; or

(2) which is a class III device because of section 360c(f) of this title,

is required to have, unless exempt under section 360j(g) of this title, an approval under this section of an application for premarket approval.

* * * *

(c) Application for premarket approval

(1) Any person may file with the Secretary an application for premarket approval for a class III device. Such an application for a device shall contain—

(A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;

(B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;

(D) an identifying reference to any performance standard under section 360d of this title which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such performance standard or adequate information to justify any deviation from such standard;

(E) such samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing;

(F) specimens of the labeling proposed to be used for such device; and

(G) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 360c of this title, may require.

* * *

Sec. 360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

* * *

SUBCHAPTER IX—MISCELLANEOUS

Sec. 393. Food and Drug Administration

* * *

(b) Mission

The Administration shall—

(1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;

(2) with respect to such products, protect the public health by ensuring that—

(A) foods are safe, wholesome, sanitary, and properly labeled;

(B) human and veterinary drugs are safe and effective;

(C) there is reasonable assurance of the safety and effectiveness of devices intended for human use;

(D) cosmetics are safe and properly labeled; and

(E) public health and safety are protected from electronic product radiation[]

* * *

TITLE 42—THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A—PUBLIC HEALTH SERVICE
SUBCHAPTER III—A—SUBSTANCE ABUSE AND
MENTAL HEALTH SERVICES ADMINISTRATION
PART A—ORGANIZATION AND
GENERAL AUTHORITY

Sec. 290aa-2. Reports: health consequences, current research, recommendations

(a) Alcoholism and alcohol abuse

The Secretary shall submit to Congress on or before January 15, 1984, and every three years thereafter a report—

(1) containing current information on health consequences of using alcoholic beverages,

(2) containing a description of current research findings made with respect to alcohol abuse and alcoholism, and

(3) containing such recommendations for legislation and administrative action as the Secretary may deem appropriate.

(b) Drug abuse

The Secretary shall submit to Congress on or before January 15, 1984, and every three years thereafter a report—

(1) describing the health consequences and extent of drug abuse in the United States;

(2) describing current research findings made with respect to drug abuse, including current findings on the health effects of marihuana and the addictive property of tobacco; and

(3) containing such recommendations for legislation and administrative action as the Secretary may deem appropriate.

* * *

Sec. 290aa-4. Data collection

(a) Requirement of annual collection of data on mental illness and substance abuse

The Secretary, acting through the Administrator, shall collect data each year on—

(1) the national incidence and prevalence of the various forms of mental illness and substance abuse; and

(2) the incidence and prevalence of such various forms in major metropolitan areas selected by the Administrator.

(b) Requisite areas of data collection on mental health

With respect to the activities of the Administrator under subsection (a) of this section, relating to mental health, the Administrator shall ensure that such activities include, at a minimum, the collection of data on—

(1) the number and variety of public and non-profit private treatment programs;

(2) the number and demographic characteristics of individuals receiving treatment through such programs;

(3) the type of care received by such individuals; and

(4) such other data as may be appropriate.

* * *

SUBCHAPTER XVII—BLOCK GRANTS

PART B—BLOCK GRANTS REGARDING MENTAL HEALTH AND SUBSTANCE ABUSE

SUBPART II—BLOCK GRANTS FOR PREVENTION AND TREATMENT OF SUBSTANCE ABUSE

Sec. 300x-26. State law regarding sale of tobacco products to individuals under age of 18

(a) Relevant law

(1) In general

Subject to paragraph (2), for fiscal year 1994 and subsequent fiscal years, the Secretary may make a grant under section 300x-21 of this title only if the State involved has in effect a law providing that it is unlawful for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under the age of 18.

(2) Delayed applicability for certain States

In the case of a State whose legislature does not convene a regular session in fiscal year 1993, and in the case of a State whose legislature does not convene a regular session in fiscal year 1994, the requirement described in paragraph 1) as a condition of a receipt of a grant under section 300x-21 of this title shall apply only for fiscal year 1995 and subsequent fiscal years.

(b) Enforcement

(1) In general

For the first applicable fiscal year and for subsequent fiscal years, a funding agreement for a grant

under section 300x-21 of this title is that the State involved will enforce the law described in subsection (a) of this section in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18.

(2) Activities and reports regarding enforcement

For the first applicable fiscal year and for subsequent fiscal years, a funding agreement for a grant under section 300x-21 of this title is that the State involved will—

(A) annually conduct random, unannounced inspections to ensure compliance with the law described in subsection (a) of this section; and

(B) annually submit to the Secretary a report describing—

(i) the activities carried out by the State to enforce such law during the fiscal year preceding the fiscal year for which the State is seeking the grant;

(ii) the extent of success the State has achieved in reducing the availability of tobacco products to individuals under the age of 18; and

(iii) the strategies to be utilized by the State for enforcing such law during the fiscal year for which the grant is sought.

(c) Noncompliance of State

Before making a grant under section 300x-21 of this title to a State for the first applicable fiscal year or any

subsequent fiscal year, the Secretary shall make a determination of whether the State has maintained compliance with subsections (a) and (b) of this section. If, after notice to the State and an opportunity for a hearing, the Secretary determines that the State is not in compliance with such subsections, the Secretary shall reduce the amount of the allotment under such section for the State for the fiscal year involved by an amount equal to—

(1) in the case of the first applicable fiscal year, 10 percent of the amount determined under section 300x-33 of this title for the State for the fiscal year;

(2) in the case of the first fiscal year following such applicable fiscal year, 20 percent of the amount determined under section 300x-33 of this title for the State for the fiscal year;

(3) in the case of the second such fiscal year, 30 percent of the amount determined under section 300x-33 of this title for the State for the fiscal year; and

(4) in the case of the third such fiscal year or any subsequent fiscal year, 40 percent of the amount determined under section 300x-33 of this title for the State for the fiscal year.

* * * *

TITLE 49—TRANSPORTATION
CHAPTER 417—OPERATIONS OF CARRIERS

Sec. 41706. Prohibitions against smoking on scheduled flights

(a) General.—An individual may not smoke in the passenger cabin or lavatory of an aircraft on a scheduled airline flight segment in air transportation or intrastate air transportation that is—

(1) between places in a State of the United States, the District of Columbia, Puerto Rico, or the Virgin Islands;

(2) between a place in any jurisdiction referred to in clause (1) of this subsection (except Alaska and Hawaii) and a place in any other of those jurisdictions; or

(3)(A) scheduled for not more than 6 hours' duration; and

(B)(i) between a place referred to in clause (1) of this subsection (except Alaska and Hawaii) and Alaska or Hawaii; or

(ii) between Alaska and Hawaii.

(b) Regulations.—The Secretary of Transportation shall prescribe regulations necessary to carry out this section.

MAR 22 1999

CLERK

In The
Supreme Court of the United States

October Term, 1998

FOOD AND DRUG ADMINISTRATION, et al.,
Petitioners,
v.

BROWN AND WILLIAMSON TOBACCO CORP., et al.,
Respondents.

On Petition For A Writ Of Certiorari
To The United States Court Of Appeals
For The Fourth Circuit

BRIEF OF THE STATES OF MINNESOTA, ALASKA,
ARIZONA, ARKANSAS, CALIFORNIA, COLORADO,
CONNECTICUT, FLORIDA, HAWAII, IDAHO,
ILLINOIS, INDIANA, IOWA, KANSAS, MAINE,
MARYLAND, MASSACHUSETTS, MICHIGAN,
MISSISSIPPI, MISSOURI, MONTANA, NEVADA,
NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO,
NEW YORK, NORTH DAKOTA, OHIO,
OKLAHOMA, OREGON, PENNSYLVANIA, RHODE
ISLAND, SOUTH DAKOTA, TEXAS, UTAH,
VERMONT, WASHINGTON, WEST VIRGINIA AND
WISCONSIN AS AMICI CURIAE
IN SUPPORT OF PETITIONERS

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Richard D. Hurt, M.D. & Channing R. Robertson, Ph.D., <i>Prying Open the Door to the Tobacco Industry's Secrets About Nicotine: The Minnesota Tobacco Trial</i> , 280 JAMA 1173 (1998)	9, 10, 11, 12

INTEREST OF THE AMICI

The thirty-nine Amici States submit this brief in support of the petition of the U.S. Food and Drug Administration (FDA) for a writ of certiorari. The States have an overwhelming interest in the vitally important question of whether the FDA has jurisdiction to regulate tobacco products under the Federal Food, Drug and Cosmetic Act (FDCA).

This Court has often recognized the States' responsibility for promoting the health, safety and welfare of their citizens. "Throughout our history the several States have exercised their police powers to protect the health and safety of their citizens. . . . [T]he 'states traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.' " *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (citations omitted); *Barsky v. Board of Regents*, 347 U.S. 442, 449 (1954) ("[A] state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power.")

Tobacco products dramatically affect the health, safety and welfare of the citizens of the Amici States. Tobacco use is the leading cause of preventable death in the United States. Tobacco products cause millions to suffer from smoking-related illnesses, including respiratory diseases, cardiovascular diseases, and cancer. In addition to the human toll, smoking imposes a huge economic burden on the states, both in terms of health care costs and in lost earnings and productivity. Despite

the overwhelming evidence of harm, tobacco use among young people is on the rise.

The States have a substantial interest in limiting access by young people¹ to tobacco products and in reducing the widespread death and disease caused by nicotine addiction, cigarettes and smokeless tobacco. The FDA's role in regulating these dangerous products is an essential complement to the State's efforts. The FDA regulations at issue in this case are fully authorized by law and perform a critical function in the comprehensive federal, state and local effort needed to prevent children from using and becoming addicted to the drug nicotine.

SUMMARY OF ARGUMENT

The FDA's petition for a writ of certiorari should be granted for three reasons. First, this case is of enormous public importance. The regulations at issue address the number one preventable public health issue of our time. Although the recent settlements between the States and the tobacco manufacturers make important strides, the FDA's regulations address matters that cannot be effectively addressed by the States alone. The Fourth Circuit's decision that the FDA lacks the authority to regulate tobacco products as drug delivery devices impedes the

¹ Because of the evidence that most tobacco-related addiction begins in childhood, FDA directed its initial regulations to reducing the use of tobacco products by young people.

FDA from joining the States in fully addressing this significant public health problem.

Second, the Fourth Circuit's decision misapplies important, well-settled principles of administrative law that require deference to the FDA's judgment and permit the FDA to determine which products fit within the broad statutory framework for regulation of "drugs" and "devices" under the FDCA. The circuit court substituted its judgment for that of the FDA, and essentially ignored the compelling – but until recently secret – evidence from the tobacco industry's own files relied upon by the FDA in asserting jurisdiction over tobacco products.

This evidence overwhelmingly shows, as Judge Hall found in his dissent, "that the companies have known about the addictive qualities of their products for years and that cigarettes are deliberately manipulated to create and sustain addiction to nicotine." Pet. A. 58a (Hall, J., dissenting).² Additional evidence the States obtained through their own litigation further exposed the industry's knowledge that its products fall squarely within the FDA's jurisdiction. Again, in the words of Judge Hall's dissent, "[t]he strength of nicotine's addictive qualities, the extent of the health problems created by tobacco products, and the complicity of the manufacturers bring us to a different place than we have been before." Pet. A. 59a.

Finally, the Fourth Circuit's decision fundamentally misconstrues the relationship between the States and the

² Reference is to the Appendix To Petition For Writ of Certiorari.

federal government. The States have enacted laws to prevent young people from using tobacco. The States also have an important role to play in implementing the Alcohol, Drug Abuse and Mental Health Administration Reorganization Act enacted by Congress in 1992. However, the federal government, through the FDA, has a vital role to play in both limiting youth access to tobacco and restricting advertising that appeals to young people. Contrary to the circuit court's conclusion, FDA regulation of tobacco products is fully authorized by the FDCA and performs a critical function in the comprehensive effort that is needed to address this important public health issue.

REASONS FOR GRANTING THE PETITION

I. THIS IS A CASE OF EXCEPTIONAL IMPORTANCE TO THE PUBLIC HEALTH AND OUR NATION'S CHILDREN.

This Court should grant review because of the exceptional public importance of this case. Every day, 3,000 American children start using tobacco regularly. Fully one-third of those who continue using tobacco products will suffer from painful, debilitating tobacco-related diseases including lung cancer, oral cancer, throat cancer, bladder cancer, cancer of the esophagus, cancer of the pancreas, heart disease, and chronic obstructive pulmonary disease. Millions of people in this country suffer from these diseases, and die prematurely, because they became addicted to the drug nicotine in the tobacco products they began to use as children. Over 400,000 individuals die each year from tobacco-related diseases. This is the

equivalent of three fully loaded 747s crashing every day, 365 days a year, with no survivors.

The Amici States confront the magnitude of the human and economic consequences of tobacco use each and every day. These consequences are enormous and, without FDA regulation, will likely grow even larger. The Amici States have all enacted laws designed to prevent young people from using tobacco products. Despite these efforts, tobacco use by young people is on the rise.

Over the past several years, more than forty State Attorneys General pursued their own litigation against the tobacco industry. Each of the States brought claims under its own state laws, in its own state courts. These lawsuits alleged a decades-long conspiracy by the tobacco industry to conceal the deadly and addictive nature of their products. The recent agreements between the States and the nation's five largest tobacco companies settling these cases achieve important advances, but do not diminish the importance of this case.³ These agreements do not address the central issue here, *i.e.* whether nicotine and tobacco products are subject to regulation by the FDA. Moreover the settlement is binding only on the signatories to the agreements. Thousands of retailers and other entities involved in the sale and distribution of

³ The terms of the recent settlement between forty-six states, five territories and the District of Columbia and the nation's five largest tobacco companies are contained on the website maintained by the National Association of Attorneys General. See <http://www.naag.org/tob2.htm>. The States of Minnesota, Florida, Texas and Mississippi had previously settled their claims against the tobacco companies.

tobacco products are not bound by the settlements. Thus, while the agreements make significant strides, the FDA rules at issue here cover important ground that the settlements with the States did not and could not address.

The circuit court does not dispute the harm caused by tobacco products; indeed, the court contends that the harm is so great, that the FDCA would require the FDA to ban the products as inherently unsafe and dangerous, rather than simply regulating them. Pet. A. 29a. The absurd conclusion that a drug is so dangerous that it cannot be regulated at all must be reviewed by this Court. The issues of Congressional intent, FDA authority, and the harms that flow from nicotine addiction are simply too important to the States, to the public health, and to the well-being of our nation's children.

II. WELL-ESTABLISHED LAW PERMITS THE FDA TO CHANGE ITS POSITION AND REGULATE TOBACCO PRODUCTS, PARTICULARLY WHERE THERE IS NEW EVIDENCE FROM THE INDUSTRY'S OWN FILES SHOWING THAT NICOTINE IS AN ADDICTIVE DRUG AND CIGARETTES ARE DRUG DELIVERY DEVICES.

The Fourth Circuit's decision should also be reviewed because its logic runs contrary to well-established administrative law, which requires deference to agency judgments and which permits the FDA to change its position on whether a product should be regulated based upon new information or if it has other sound reasons for doing so. The district court properly applied these well-established principles. Pet. A. 90a-92a.

It is axiomatic that the FDA has the authority under the FDCA to regulate drugs⁴ and devices.⁵ It is also beyond dispute that Congress has delegated to the FDA the responsibility of determining, based on the evidence, which specific products meet the statutory definitions. The FDA properly determined that tobacco products fall within the statutory standards for both "drug" and "device," and are therefore subject to regulation under the FDCA. The FDA's jurisdictional determination was based on an overwhelming factual record demonstrating that nicotine is a drug, and that the tobacco manufacturers deliberately design and market their products to promote the addictive properties of nicotine. See, e.g., *Jurisdictional Determination*, 61 Fed. Reg. 44,619, 44,854-994 (1996); *Jurisdictional Analysis*, 60 Fed. Reg. 41,453, 41,583-784 (1995). As the FDA explained in the rulemaking record, "[t]he quality, quantity, and scope of the evidence available to FDA today is far greater than any other time when FDA has considered regulation of cigarettes and smokeless tobacco products." 60 Fed. Reg. at 41,464 n.1.

⁴ The term "drug" is defined to include not only "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," but also "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1).

⁵ The term "device" includes "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article . . . intended to affect the structure or any function of the body of man or other animals . . . and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h).

The FDA's well-reasoned and extensively documented basis for regulating tobacco products is entitled to deference. *Chevron, U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 844 (1984) ("We have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer"). Moreover, that the FDA chose not to regulate nicotine sooner does not preclude it from doing so now. "An initial agency interpretation is not instantly carved in stone. On the contrary, the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis." *Id.* at 863-64; *Rust v. Sullivan*, 500 U.S. 173, 186-87 (1991) ("An agency is not required 'to establish rules of conduct to last forever' . . . but rather 'must be given ample latitude to adapt its rules and policies to the demands of changing circumstances.' " (citations omitted)).

In fact, the FDA's regulation of tobacco products is long overdue. The change in the FDA's position concerning regulation of the drug nicotine and the drug delivery device of tobacco products is based in large part upon compelling new evidence from the tobacco industry's heretofore secret internal files. If the government had known earlier what the industry knew and conspired to conceal for years – about the addictiveness of nicotine, about the industry's efforts to manipulate levels of nicotine, and about the industry's efforts to target young people – the FDA may well have acted much sooner.

The suits by the Amici States against the tobacco industry have resulted in the production of even more previously secret evidence from the tobacco industry's

own files. Minnesota's case alone produced over 33 million pages of documents in depositories in Minnesota and England, as well as approximately 40,000 more documents over which the industry had claimed an attorney-client privilege.⁶ These documents, the majority of which had not been produced by the industry before, fully confirm the FDA's position that nicotine is a drug; that cigarettes are drug delivery devices; and that the tobacco industry has known and studied for years how to manipulate, and maximize, the impact of nicotine on the addicted smoker. A recently published article in the *Journal of the American Medical Association* sets forth many representative tobacco industry documents relating to the issues of addiction, cigarette design and nicotine manipulation.⁷ The authors conclude, based on their review of thousands of pages of industry documents, that the industry knew for decades of the addictiveness of nicotine and perpetuated that addiction through manipulation of nicotine.⁸ Several of the exhibits in Minnesota's trial against the industry, discussed in the JAMA article, illustrate why the Amici States believe so strongly that Supreme Court review of this case is warranted:

⁶ The tobacco manufacturers and tobacco-related organizations that are parties to the recent national settlement with many of the Amici States have agreed to maintain internet document websites accessible through "TobaccoResolution.com" where documents produced in the States' litigation will be accessible to the public.

⁷ Richard D. Hurt, M.D. & Channing R. Robertson, Ph.D., *Prying Open the Door to the Tobacco Industry's Secrets About Nicotine: The Minnesota Tobacco Trial*, 280 JAMA 1173 (1998) ("Hurt & Robertson").

⁸ *Id.* at 1180.

- A "CONFIDENTIAL" 1969 memo written to Phillip Morris research director Dr. Helmut Wakeham:

I would be more cautious in using the pharomic-medical model – do we really want to tout cigarette smoke as a drug? It is, of course, but *there are dangerous F.D.A. implications to having such conceptualization go beyond these walls.*⁹

- A "CONFIDENTIAL" Research Planning Memorandum written in 1972 by Claude E. Teague, Jr., assistant director of research at R.J. Reynolds, entitled "The Nature of the Tobacco Business and the Crucial Role of Nicotine Therein":

In a sense, the tobacco industry may be thought of as being a specialized, highly ritualized and stylized segment of the pharmaceutical industry. Tobacco products, uniquely, contain and deliver nicotine, a potent drug with a variety of physiological effects. . . . *Thus, a tobacco product is, in essence, a vehicle for delivery of nicotine, designed to deliver the nicotine in a generally acceptable and attractive form.* Our Industry is then based upon design, manufacture and sale of attractive dosage forms of nicotine, and our Company's position in our Industry is determined by our ability to produce dosage forms of nicotine which have more overall value,

⁹ *Id.* at 1176 (emphasis added).

tangible or intangible, to the consumer than those of our competitors.¹⁰

- A 1972 Phillip Morris memorandum summarizing the discussion at a conference attended by 25 scientists from England, Canada and the United States:

The majority of conferees would accept the proposition that nicotine is the active constituent of cigarette smoke. . . . The cigarette should be conceived not as a product but as a package. The product is nicotine. Think of the cigarette pack as a storage container for a day's supply of nicotine. . . . Think of the cigarette as a dispenser for a dose unit of nicotine. . . . Think of a puff of smoke as the vehicle of nicotine. . . . Smoke is beyond question the most optimized vehicle of nicotine and the cigarette the most optimized dispenser of smoke.¹¹

These documents, and many others like them, underscore the overwhelming record compiled by the FDA in the course of promulgating the administrative rules at issue here. The documents convincingly establish that nicotine is a drug that, in the words of the FDCA, "affects the structure or any function of the body." Moreover, the evidence convincingly demonstrates that the tobacco

¹⁰ *Id.* at 1175 (emphasis added). This document was cited by the FDA in support of its regulation of tobacco products. See 60 Fed. Reg. 41,453, 41,617-18 (1995) (quoting from New York Times newspaper report).

¹¹ Hurt & Robertson, *supra* n. 7 at 1176; 60 Fed. Reg. 41,453, 41,617 (1995).

manufacturers fully intend this result, and deliberately manipulate the nicotine levels in their products to maximize its effect and promote addiction. The FDA properly determined based upon a comprehensive and exhaustive review of the evidence that tobacco products meet the requisite statutory definitions and are subject to regulation under the FDCA. The circuit court's decision failed to give the FDA's judgment the deference that it was entitled to receive. *See Chevron*, 467 U.S. at 844.

The Amici States urge this Court to grant the FDA's petition to review this case to consider the agency's assertion of jurisdiction over tobacco products. The tobacco companies long ago understood that "we are in a nicotine rather than a tobacco industry,"¹² and at least one suggested that it "should learn to look at itself as a drug company rather than as a tobacco company."¹³ This Court should review the Fourth Circuit's decision precluding the FDA from responding to new evidence to regulate tobacco products because, in the words of Judge Hall's dissent, "the 'cold hard facts' are now in." Pet. A. 64a.

¹² Hurt & Robertson, *supra* n.7 at 1176.

¹³ *Id.*

III. THE FOURTH CIRCUIT'S DECISION FUNDAMENTALLY MISCONSTRUES THE IMPACT OF STATE REGULATION OF TOBACCO PRODUCTS: THE LAW PERMITS, AND THE PROBLEM DEMANDS, A COMPREHENSIVE FEDERAL, STATE AND LOCAL EFFORT.

Finally, this Court should review the Fourth Circuit's decision because the lower court misconceives the relationship between the States and the federal government. The circuit court found that Congress, through the Alcohol, Drug Abuse and Mental Health Administration Reorganization Act of 1992 (ADAMHA amendments), expressed "clear congressional intent that States exercise their traditional police powers and take a primary role in attacking the problem of youth access to tobacco products." Pet. A. 51a. The court concluded that the FDA does not have jurisdiction over tobacco because there is an "inherent conflict" between the FDA's regulations and the primary state regulatory role allegedly established by Congress in the ADAMHA amendments. *Id.*

The circuit court's analysis is flawed for several reasons. First, as the district court and the dissenting judge at the Fourth Circuit properly observed, the ADAMHA amendments merely establish conditions for the receipt of federal funds; they "do not represent an all-encompassing last-word pronouncement of federal policy on underage smoking." Pet. A. 100a, 69a-70a.

Second, even assuming the ADAMHA amendments signal an intent by Congress that States regulate underage tobacco use, the FDA regulations permit continued state enforcement of many laws affecting youth access to tobacco including, for example, restrictions on the sale or

distribution of tobacco products, restrictions on smoking in public places, penalties on underage smokers and age restrictions on persons who sell tobacco. 61 Fed. Reg. 44,396, 44,549 (1996). "An overlap between two regulatory systems does not require wholesale jettisoning of one in favor of the other." Pet. A. 70a (Hall, J., dissenting).

Third, even those state laws which might be preempted could qualify for exemption, thereby further minimizing conflicts. 61 Fed. Reg. 44,396, 44,548-50; 21 U.S.C. § 360k(b). The FDA has stated that its regulations set only a floor for regulation of youth access to tobacco products, and that "[f]ederal cooperation with, and continued reliance upon, innovative and aggressive state and local enforcement efforts is essential." 61 Fed. Reg. at 44,548.

Finally, while the States have done a great deal to address the problems of tobacco use, federal food and drug regulation has co-existed with state regulation for years. Although the States unquestionably play an essential role in regulating matters pertaining to public health and safety, the federal government also has a very significant role. *Medtronic*, 518 U.S. at 475 ("Despite the prominence of the States in matters of public health and safety, in recent decades the Federal Government has played an increasingly significant role in the protection of the health of our people"). The general design of food and drug regulation allows for complementary state and federal jurisdiction. The circuit courts have recognized this complementary jurisdiction in holding that, while the FDCA is important in setting uniform national standards, the act

does not preclude the States from also regulating products subject to FDA authority.¹⁴

The ADAMHA amendments do not preclude the FDA from regulating nicotine. FDA regulation of tobacco products is no different than FDA regulation of the many other drugs and devices which are, in the language of the FDCA, "intended to affect the structure or function of the body." While tobacco products may be "different from the run-of-the-mine drugs and devices in the FDA's bailiwick," Pet. A. 74a (Hall, J., dissenting),

the FDCA was broadly worded by design. In an area in which complex new products (and old products, seen in the light of new evidence) pose the potential for grievous harm, Congress deemed it necessary to delegate to an expert – the FDA – the job of monitoring drugs. Cigarettes and smokeless tobacco clearly fit within the literal terms of the FDCA. Absent a showing that following these statutory terms would be absurd or somehow frustrate congressional intent, [the Court is] bound to uphold FDA jurisdiction.

Id. at 70a-71a.

¹⁴ See, e.g., *Smith v. Pingree*, 651 F.2d 1021, 1025 (5th Cir. 1981) (FDCA does not preempt Florida statute concerning the fitting and selling of hearing aids. "Because the federal requirements did not regulate every aspect of this area, the state had the implied reservation of power to fill out the scheme."); *Pharmaceutical Soc. of State of New York, Inc. v. Lefkowitz*, 586 F.2d 953, 958 (2d Cir. 1978) (State law not preempted by the FDCA. "The [FDCA] is not so pervasive as to remove the states entirely from the field of drug regulation.").

The FDA's authority to regulate tobacco products is authorized by law, and is a critically important part of the traditional complementary federal and state regulation of matters affecting public health and safety. The FDA access regulations constitute uniform national standards which the States may build upon. Given the magnitude of the problem, the ADAMHA amendments alone are not enough. The amendments address only the issue of youth access to tobacco products. More is needed, including advertising and promotion restrictions, restrictions on retailers, and additional educational efforts directed at children. The FDA regulations are an important step in the right direction. When combined with the ADAMHA amendments and other federal laws, current laws at the state and local level, the advances achieved through State litigation against the tobacco industry, and additional efforts to be undertaken in the future, the FDA's regulations will help limit the number of American youth who become addicted to nicotine. Millions of individuals will benefit, both now and in the future.

The Amici States urge this Court to review this case because the Fourth Circuit's decision is contrary to law, and affects the most important public health issue of this generation.

CONCLUSION

For all the foregoing reasons, the thirty-nine Amici States respectfully request that the petition for a writ of certiorari be granted.

March, 1999

Respectfully submitted,

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Supreme Court, U.S.

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In the Supreme Court of the United States

OCTOBER TERM, 1998

FOOD AND DRUG ADMINISTRATION, ET AL.,
PETITIONERS

v.

BROWN AND WILLIAMSON TOBACCO CORP., ET AL.

*ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT*

REPLY BRIEF FOR THE PETITIONERS

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PETITIONERS

v.

BROWN AND WILLIAMSON TOBACCO CORP., ET AL.

*ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT*

REPLY BRIEF FOR THE PETITIONERS

A. The Food and Drug Administration seeks certiorari in this case because the court below incorrectly resolved an issue of exceptional public importance. That issue is whether FDA has authority to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. 301 *et seq.*, given FDA's findings that the nicotine in tobacco products is intended by manufacturers to have substantial effects on the structure and function of the human body, including sustaining a user's addiction and acting as a sedative, stimulant, and appetite suppressant.

In recognition of the overriding public importance of that issue, 39 States have joined a brief as amici curiae urging the court to grant FDA's petition. The States agree that review is warranted because the case is of "enormous public importance"; the decision below "misapplies important, well-settled principles of administrative law"; and the decision "fundamentally misconstrues the relationship between the States and the federal government." States' Br. 2, 3-4.

Respondents do not deny the importance of the question presented. Instead, they argue that the question is of such exceptional public importance that only Congress should resolve it. Congress, however, has already given FDA authority under the Act to regulate "drug[s]" and "device[s]." 21 U.S.C. 321(g)(1) (C) and (h)(3). And, after the most important rule-making in its history, FDA has determined that tobacco products are subject to regulation as both. The question whether FDA's determination falls within the authority that Congress has already conferred on it is uniquely one for the courts, not for Congress.

Respondents also argue that the decision of the court of appeals is correct. We address below respondents' attempts to defend the decision below. Before we do, however, we note that the decision whether to grant certiorari does not depend on how the question presented ultimately should be resolved. For purposes of granting certiorari, it is only necessary to conclude that the court below resolved "an important question of federal law that has not been, but should be, settled by this Court." Sup. Ct. R. 10(c). That standard is plainly satisfied here. The question whether FDA has authority to regulate the product that is the leading cause of preventable death in the United States, 61 Fed. Reg. 44,398 (1996), should not be left to a single regional court of appeals. A question of such momentous importance should be finally resolved by this Court.

B. Respondents contend (see, *e.g.*, Br. in Opp. 21-23) that the decision below is correct because, in their view, Congress unambiguously made clear that tobacco products as customarily marketed are not "drug[s]" or "device[s]" within the meaning of the Act. That argument cannot be reconciled with (i) the Act's controlling definitions of "drug" and "device," which define those terms to include products that are "intended to affect the structure or any function of the body," 21 U.S.C. 321(g)(1)(C) and (h)(3); (ii) FDA's detailed findings that the nicotine in tobacco products is intended by

tobacco manufacturers to have significant effects on the structure and function of the body, including satisfying a user's addiction, and acting as a sedative, stimulant, and appetite suppressant; (iii) the absence of any exemption for tobacco products from the controlling definitions of "drug" and "device," in contrast to the Act's express exemption of tobacco products from the definition of "dietary supplement," 21 U.S.C. 321(ff)(1); and (iv) the similarity between tobacco products and other products indisputably subject to FDA regulation under the Act.

1. Because the language of the "drug" and "device" definitions, when applied to FDA's findings, provides such compelling support for FDA's determination that tobacco products are covered by the Act, it is not surprising that respondents in their 28-page opposition never once quote the controlling definitions. Nor is it surprising that respondents never once directly confront FDA's specific findings about the effects of nicotine on the structure and function of the human body intended by tobacco manufacturers. The force of the controlling definitions and FDA's findings does not dissipate, however, simply because respondents refuse to acknowledge them. As we explain in our petition (at 16-18), they constitute the key to a correct decision in this case.

At the very least, the Act's definitions, when applied to FDA's findings, completely undermine respondents' argument that the present case can be resolved in their favor at step one of the analysis set forth in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Given those definitions and findings, it simply is not possible to conclude that Congress specifically addressed the question and clearly denied FDA authority to regulate tobacco products. And, once it is accepted that the present case must be resolved at step two of *Chevron*, the result is clear. FDA reasonably determined that tobacco products are subject to regulation under the Act.

2. FDA's judgment does not, however, rest only on the application of the plain language of the Act to FDA's thoroughly documented findings that the nicotine in tobacco products is intended by tobacco manufacturers to sustain addiction and act as a sedative, stimulant, and appetite suppressant. FDA also relied on the similarity of tobacco products to other products that are covered by the Act, including tranquilizers (such as Valium), stimulants (such as NoDoz), weight-loss products (such as Dexatrim), narcotics used to treat addiction (such as methadone), and nicotine replacement products (such as nicotine inhalers).

Respondents attempt (Br. in Opp. 13) to distinguish those products on the ground that they are marketed with therapeutic claims, while tobacco products are marketed only to provide smoking pleasure. That distinction, however, finds no support in the text of the Act or in its public health purposes. The text of the Act makes "intended" effect, not "market claims," the decisive factor. 21 U.S.C. 321(g)(1)(C) and (h)(3). Coverage of tobacco products therefore does not depend on whether a manufacturer expressly represents that tobacco products satisfy an addictive need or act as a sedative, stimulant, or appetite suppressant. While such claims would be sufficient to establish intended effect, they are not the only bases for such a finding. When, as here, manufacturers know that most consumers use tobacco products to satisfy addiction and to obtain other physiological effects, and manufacturers engineer their products to deliver the amount of nicotine necessary to sustain addiction, an intended effect on the structure and function of the body is equally apparent. Tobacco manufacturers may not escape regulation by relying on a euphemistic market claim that cigarettes are intended for smoking pleasure.¹

¹ Respondents refer (Br. in Opp. 25) to FDA's finding of intent as resting on the foreseeability of the effects of tobacco products. FDA's finding of intended effects, however, does not rest on foreseeability alone. As noted above, FDA also relied on evidence that tobacco manufacturers

From a public health perspective, no other result could be justified. The risks to the public health and the appropriateness of regulation under the Act exist regardless of whether the intended effect is established through market claims or by other evidence. Under respondents' view, FDA would not have been able to regulate "caine," an imitation cocaine product that was marketed as incense, or "khat," an imported stimulant that was sold without any market claim. 61 Fed. Reg. at 45,167 (explaining that those products were regulated because they were found to have intended effects on the body based on, *inter alia*, widespread consumer use of the products for their physiological effects). Indeed, if respondents were correct in their understanding of the Act, the marketers of nicotine inhalers could escape FDA regulation as long as they eliminated any therapeutic claims and marketed their products as providing "breathing pleasure." FDA correctly rejected such an approach as inconsistent with the text of the Act and its public health purposes.

3. Because the nicotine in tobacco products falls within the core of FDA's regulatory authority, respondents are also mistaken in asserting (Br. in Opp. 26) that FDA's interpretation of the Act would expand its application to products such as thermal pajamas and air conditioners. Those examples raise the question whether it would be reasonable to rely on the plain language of a definition when it leads to an application that is far removed from the ordinary understanding of the term that is being defined. See *Gustafson v. Alloyd Co.*, 513 U.S. 561, 574-576 (1995). This case, however, does not raise that question. In ordinary usage, no one would say that thermal pajamas and air conditioners have drug-like effects. By contrast, as internal

have long known that consumers use tobacco products to sustain addiction and for their other physiological effects, and on evidence that manufacturers have designed their products to produce the dosage of nicotine necessary to sustain addiction, as well as evidence of actual consumer use for drug-like effects.

industry documents in the record make clear, manufacturers of tobacco products have long characterized the nicotine in tobacco products as having such effects, while denying such effects publicly. See Pet. 5.

C. 1. Respondents' remaining efforts to avoid the force of the controlling definitions and FDA's findings are also unpersuasive. For example, respondents attempt (Br. in Opp. 9-12) to draw support for their position from FDA's refusals in 1977 and in 1980 to regulate tobacco products as "drug[s]" or "device[s]." But an agency is always free to change its interpretation of a statute or its position on an issue, *Rust v. Sullivan*, 500 U.S. 173, 186-187 (1991); *Chevron*, 467 U.S. at 863-864, as long as it provides a reasonable explanation for the change. FDA satisfied that obligation by explaining the circumstances that led to its change in position.

First, while no major health organization had determined that nicotine was an addictive drug before 1980, by 1994 every leading scientific panel or organization had concluded that nicotine "is addictive or dependence-producing." 61 Fed. Reg. at 45,228. Second, since 1980 scientific evidence has shown that as many as 92% of all smokers and 75% of smokeless tobacco users are addicted; and slightly less than three-quarters of all cigarette smokers and more than one-half of all smokeless tobacco consumers use those products as a sedative. *Id.* at 45,233-45,234. In contrast, before 1980 evidence regarding the proportion of users who were addicted was extremely limited, and the evidence was insufficient to conclude that tobacco products were consumed primarily for their pharmacological effects. *Id.* at 45,234-45,235. Third, recently released internal industry documents show that tobacco manufacturers have long known that consumers use tobacco products primarily to sustain addiction and for their other pharmacological effects, and that manufacturers have engineered their products to deliver active doses of nicotine. *Id.* at 45,235-45,236. Almost

none of that evidence was publicly available in 1980. *Id.* at 45,237. FDA's change in position was therefore "based on an overwhelming body of new evidence that ha[d] become available since FDA last considered this issue." *Ibid.*²

Respondents contend (Br. in Opp. 13) that FDA's 1977 and 1980 decisions were not based on the absence of the evidence discussed above, but on a categorical view that tobacco products are not covered by the Act absent specific health claims. Respondents have misread those decisions.

In its 1977 decision rejecting a petition filed by Action on Smoking & Health (ASH) to regulate cigarettes based on ASH's assertions concerning how consumers use them, FDA stated that "FDA can assert jurisdiction over cigarettes containing nicotine (or nicotine separately) when a jurisdictional basis for doing so exists, *e.g.*, health claims made by the vendors." Letter from Donald Kennedy, FDA Commissioner, to John F. Banzhaf, III, ASH Executive Director 1 (Dec. 5, 1977). In its brief defending the decision, the government explained that FDA had concluded that cigarettes could not be regulated as drugs "in the absence of health claims by the manufacturers or vendors or other evidence of the manufacturers' or vendors' intent to affect the bodily structure or function." Appellees C.A. Br. at 14, *Action on Smoking & Health v. Harris*, No. 79-1397 (emphasis added). And, in affirming FDA's decision, the D.C. Circuit stated that "we do not read [FDA's decision] to mean either that the Commissioner will never consider evidence of consumer intent on this question or that he simply ignored

² Because the evidence discussed above was not available in 1938, when the Act was passed, or in 1964, when the Surgeon General issued his report, respondents err in asserting that application of FDA's legal standard for determining coverage under the Act would have led FDA to conclude in 1938 and 1964 that tobacco products were covered. Respondents' reliance (Br. in Opp. 24-25) on the Surgeon General's 1964 Report is particularly puzzling given the report's (erroneous) conclusion that smoking is not addictive.

the evidence presented to him in this petition." *Action on Smoking & Health v. Harris*, 655 F.2d 236, 239 (1980). Instead, the petition failed because ASH had failed to "meet the high standard established in cases where the statutory 'intent' is derived from consumer use alone." *Ibid*.

Similarly, in rejecting ASH's second petition in 1980, FDA stated:

ASH asserts that objective evidence other than manufacturers' claims can be material to a determination of intended use under the statutory definition. * * * We agree. * * * [E]vidence of consumer use can be one element of objective evidence to be weighed in determining if the intended purpose of a product subjects it to regulation under the Act. ASH has not established that consumers use attached cigarette filters * * * to the extent necessary to allow FDA to impute the requisite intended uses to manufacturers or vendors.

Letter from Jere E. Goyan, FDA Commissioner, to John F. Banzhaf, III, ASH Executive Director 8-9 (Nov. 25, 1980). In light of the above, we do not understand how respondents can assert (Br. in Opp. 13) that "[n]one of FDA's statements disavowing jurisdiction relied on * * * lack of evidence."

2. Respondents contend (Br. in Opp. 17) that Congress could not have intended to give FDA authority to ban tobacco products. FDA, however, has not taken any steps to ban tobacco products. The regulatory actions at issue here are FDA's prohibition on the sale of tobacco products to minors and certain access and advertising restrictions that are aimed at preventing circumvention of that prohibition. The question whether FDA has authority to ban the sale of tobacco products to adults is therefore not presented.

Respondents argue (Br. in Opp. 23-24) that, if tobacco products are covered by the Act, FDA would necessarily have to ban their sale altogether. From that premise, respondents contend that Congress could not have intended for FDA to have *any* authority over tobacco products. The

premise of respondents' argument is simply incorrect. As we note in our petition, FDA determined that, even though tobacco products cause serious adverse health consequences, their sudden withdrawal "would be dangerous," both because the health care system "would be overwhelmed by * * * treatment demands," and because of the likely development of black market tobacco products "even more dangerous than those currently marketed." 61 Fed. Reg. at 44,413. Based on those findings, FDA concluded that a ban on the sale of tobacco products to adults is neither appropriate nor required under the Act. See Pet. 3, 8-9.

Since FDA is entitled to *Chevron* deference on its interpretation of the Act, FDA's conclusion that the Act does not require it to ban the sale of tobacco products to adults must be upheld unless Congress "directly" and "unambiguously" provided otherwise. 467 U.S. at 842, 843. Far from demonstrating such a clear and unambiguous congressional intent, respondents have not identified any language in the Act that removes FDA's discretion to enforce the Act so as to avoid the harmful health consequences of a total ban. Indeed, they do not even cite the provisions of the Act and regulations on which FDA reasonably relied in weighing the health risks of permitting continued sales of tobacco products to adults against the health risks of prohibiting such sales. See Pet. 23 (citing 21 U.S.C. 360c(a)(2)(C) and 21 C.F.R. 860.7(d)(1)).

3. Respondents' reliance (Br. in Opp. 8-9, 25-26) on certain tobacco-specific statutes as evidence that FDA has no authority to regulate tobacco products is similarly misplaced. Respondents' misreading of the Federal Cigarette Labeling and Advertising Act (FCLAA), Pub. L. No. 89-92, 79 Stat. 282, which requires certain warning labels on cigarettes, see 15 U.S.C. 1333, illustrates the mistake in respondents' approach. FCLAA precludes FDA from requiring warning labels different from those prescribed by that statute. See 15 U.S.C. 1334(a) ("No statement relating to smoking and health, other than the statement required by

[Section 1333], shall be required on any cigarette package.”). But the text of FCLAA does not limit FDA’s authority to regulate tobacco products in any other way. In particular, it does not remotely suggest that FDA lacks authority to prohibit the sale of cigarettes to minors or to promulgate advertising restrictions designed to prevent circumvention of that prohibition. For that matter, FCLAA does not limit any authority of FDA to ban tobacco products altogether, just as it does not limit the authority of a State to do so. As the Court explained in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992), FCLAA “merely prohibit[s] state and federal rulemaking bodies from mandating particular cautionary statements on cigarette labels.” FCLAA therefore provides no support for respondents’ challenge to the regulatory program at issue here. Respondents’ reliance on the other tobacco-specific statutes suffers from the same basic flaw. See Pet. 27.

4. Finally, respondents contend (Br. in Opp. 27-28) that FDA’s regulation of tobacco products would impermissibly intrude on state authority to regulate tobacco products. Thirty-nine States, however, strongly disagree. As the States explain in their amicus brief (at 4), “FDA regulation of tobacco products is fully authorized by the FDCA and performs a critical function in the comprehensive effort that is needed to address this important public health issue.”

* * * * *

For the reasons discussed above as well as those set forth in our petition, it is respectfully submitted that the petition for a writ of certiorari should be granted.

SETH P. WAXMAN
Solicitor General

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AMICUS CURIAE
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INTEREST OF AMICUS CURIAE¹

Amicus Curiae, Action on Smoking and Health (ASH) is the oldest and largest anti-smoking organization in the country dedicated solely to the issues to tobacco and smoking. ASH is a national non-profit scientific and educational organization that for over 30 years has focused on the problems of tobacco, and protecting the rights of non-smokers not to have to breathe in other persons' tobacco smoke. ASH and its Executive Director, John F. Banzhaf III, have brought many legal actions related to smoking, including *Banzhaf v. FCC*, 405 F.2d 1082 (D.C. Cir. 1968) (upholding FCC ruling that television and radio stations must provide substantial free time for anti-smoking messages), *Capital Broadcasting Co. v. Mitchell*, 333 F. Supp. 582 (D.C. 1971) (upholding enforcement of the federal statute which prohibits cigarette advertising on any medium of electronic communication subject to jurisdiction of the Federal Communications Act), *National Association of Motor Bus Owners v. United States*, 370 F. Supp. 408 (D.D.C. 1974) (upholding ICC regulation restricting smoking on buses traveling in interstate commerce as a proper exercise of ICC jurisdiction and a reasonable exercise of ICC's rule-making authority), and *ASH v. CAB*, 699 F.2d 1209 (D.C. Cir. 1983) (requiring former Civil Aeronautics Board to

¹ John F. Banzhaf III, Chief Counsel and Kathleen E. Scheg, Legislative Counsel authored the brief for ASH. No counsel for either party authored the brief in whole or in part and no one apart from ASH's donor members made a monetary contribution to the preparation or submission of this brief.

Consent to the filing of this brief has been granted by the parties. Their letters of consent are attached.

adopt reasonable regulations for non-smoking sections on airplanes, since expanded to a ban on smoking on almost all domestic flights).

ASH has a special interest in the instant case because over 20 years ago, in 1977, Action on Smoking and Health petitioned the FDA to regulate tobacco products as "drugs". In 1978, ASH again petitioned the FDA to regulate cigarettes, this time as "devices," under the Federal Food, Drug, and Cosmetic Act (FDCA), ch. 675, 52 Stat. 1040, 21 U.S.C. 301 et seq. These petitions led to the decision of the court in *ASH v. Harris*, 655 F.2d 236 (D.C. Cir. 1980) which in ASH's opinion has been misconstrued by the majority in the Fourth Circuit in the instant case.

Moreover, ASH's 32 years of knowledge and experience in addressing issues related to tobacco products puts it in a unique position to assist the Court in understanding the importance to the public of the Court granting a writ of certiorari in this case. Underlying the legal issues presented in this case is the source of the leading preventable cause of death, disease and disability in the Nation. There is no more important public health issue, and the authority of the FDA to regulate tobacco products will affect millions of people well into the next millennium.

SUMMARY OF ARGUMENT

Amicus Curiae, Action on Smoking and Health (ASH) urges the court to grant the Food and Drug Administration's (FDA) Petition for Writ of Certiorari. ASH supports the FDA Petition because the case is of utmost public importance, and because there is a conflict between this case from the Fourth Circuit and an earlier case from the United States Court of Appeals, District of

Columbia Circuit, namely *ASH v. Harris*, 655 F.2d 236 (D.C. Cir. 1980).

The instant case is of utmost public importance. Tobacco products, which the FDA seeks to regulate, are the leading preventable cause of death in the United States, killing over 400,000 people a year. The FDA regulation of tobacco products can also have a significant impact on the U.S. economy, which now incurs over \$130 billion a year from medical and other costs caused by smoking-related illnesses.

The conflict between the Fourth Circuit and the District of Columbia Circuit is over the authority of the FDA to regulate tobacco products and the deference the courts should give to the agency's interpretation of its own statute, the Federal, Food, Drug and Cosmetic Act, (FDCA) ch. 675, 52 Stat. 1040, 21 U.S.C. 321 et seq. While the D.C. Circuit looked to the language of the statute, deferred to the agency's interpretation, and allowed for subsequent revision of that interpretation in light of new information, the Fourth Circuit has refused to defer to the FDA's interpretation of its own statute. Instead, it has relied on extrinsic evidence, including a convoluted and incomplete analysis of Congressional inaction.

I. MAJOR PUBLIC HEALTH AND ECONOMIC ISSUE

The question presented in this case, whether the FDA has authority to regulate tobacco products, is of critical importance to the public health and to the economy of this nation. As former U.S. Secretary of Health, Education and Welfare, Joseph Califano stated in testimony before the House Energy and Commerce Committee's Subcommittee on Health on May 17, 1994:

Had we known what the tobacco companies knew and had we been privy to their research on the addictive nature of nicotine and their ability to manipulate the amount of nicotine in cigarettes, the 1979 Surgeon General's report would have found cigarettes addictive and we would have moved to regulate them. Unfortunately, the President of the United States, the Secretary of Health, Education, and Welfare, and the Surgeon General of the United States were all victims of the concealment and disinformation campaign of the tobacco companies.

A. Public Health Importance

This case is of immense public health importance because the use of tobacco products is the single leading cause of death in the United States.² Over 400,000 Americans die each year from tobacco diseases.³ This is more than the combined deaths each year from AIDS, car accidents, alcohol, homicides, illegal drugs, suicides and fires.⁴

Moreover, smoking is predominately a "pediatric disease." A person who does not initiate tobacco use as a minor is unlikely to begin as an adult. Despite the fact that the sale of tobacco products to minors is illegal in all 50 states, over 80 percent of smokers begin smoking

² Lynch, Barbara S., and Bonnie, Richard J., eds., *Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths*, Institute of Medicine, National Academy Press, Washington, D.C., 1994., p. 3. (Hereafter referred to as IOM.)

³ "Cigarette Smoking - Attributable Mortality and Years of Potential Life Lost - United States, 1990," *MMWR*, CDC, DHHS, 42(33):645-649.

⁴ IOM, op. cit., p. 3.

before age 18, and more than half become regular smokers while still a minor.⁵ Currently, approximately 3 million American children smoke,⁶ and each year another 1 million minors become regular smokers.⁷ Approximately one third of these children will eventually die as a result of their tobacco use.⁸ This is truly a national tragedy.

B. Important Economic Ramifications

These deaths caused by tobacco use often are preceded by lengthy periods of illness, imposing an extraordinary burden on the United States economy in health care costs and lost productivity,⁹ and thus making the

⁵ U.S. Surgeon General, *Preventing Tobacco Use Among Young People: A Report of the Surgeon General*, U.S. Government Printing Office, Washington, D.C., 1994, p. 65. (hereafter referred to as SGR 1994.)

⁶ 1994 SGR, op. cit. p. 5.

⁷ IOM Report, op. cit., p. 8.

⁸ Memorandum from Michael P. Erickson (CDC) to Catherine Lorraine (FDA) August 7, 1995, and CDC Fact Sheet; citing Pierce, J.R., M.C. Fiore, T.E. Novotny, E.J. Hatziandreu, and R.M. Davis, Trends in Cigarette Smoking in the United States: Projections to the Year 2000, *JAMA* 261:61-65, 1989; Unpublished data from the 1986 National Mortality Followback Survey, CDC, OSH; Peto, R., A.D. Lopez, J. Boreham, M. Thun, and C. Heath, "Mortality from Smoking in Developed Countries, 1950-2000: Indirect Estimates from National Vital Statistics," Oxford University Press, Oxford, 1994.

⁹ See generally U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Office on Smoking and Health, *Reducing the Health Consequences of Tobacco: 25 years of Progress, A Report of the Surgeon General* (Atlanta, Georgia: U.S. Government Printing Office, 1989); U.S.

case of great public importance also to the economy of the Nation. According to a recent analysis conducted by the United States Department of the Treasury, smoking will cost the nation \$130 billion a year, of which \$45 million is attributable to medical costs due to smoking related diseases.¹⁰

These twin tragedies of devastating personal loss due to death and disease caused by tobacco use, and the immense financial cost for the U.S. economy, make regulation of tobacco products by the FDA an issue of extreme public importance. It is one of the reasons why ASH supports the FDA petition for a writ of certiorari in this case.

C. Demonstration of Public Importance

The immense public importance is also why national health experts and leading public health organizations have all strongly supported the FDA regulation of tobacco products. Most significantly, the Advisory Committee on Tobacco Policy and Public Health, co-chaired by former U.S. Surgeon General C. Everett Koop, M.D., Sc.D., and former FDA Commissioner David A. Kessler, M.D., and composed of the leaders in tobacco control

Department of Health and Human Services, Centers for Disease Control and Prevention, Office on Smoking and Health, Preventing Tobacco Use Among Young People, A Report of the Surgeon General (Atlanta, Georgia: U.S. Government Printing Office, 1994.)

¹⁰ 144 Cong. Rec. S6007-2 (daily ed. June 10, 1998) (statement of Senator Kennedy) referring to "the Economic Costs of Smoking in the United States and the Benefits of Comprehensive Tobacco Legislation", a report of the Department of the Treasury, March 1998.

from the major public health groups,¹¹ concluded unanimously that the FDA should have unrestricted authority to regulate tobacco products. After noting that "nicotine in cigarettes and smokeless tobacco has the same pharmacological effects as other drugs that FDA has traditionally regulated,"¹² the Advisory Committee recommended:

- FDA should continue to have authority to regulate all areas of nicotine, as well as other constituents and ingredients, and that authority should be made completely explicit.
- FDA should continue to have the authority to phase out nicotine and remove ingredients that contribute to the initiation of smoking and dependence on cigarettes and other tobacco products (including smokeless tobacco, pipes, cigars, and roll-your-own tobacco), and that authority should be made completely explicit.

¹¹ These include: Action on Smoking and Health, Advocacy Institute, Amer. Acad. of Family Physicians, Amer. Academy of Pediatrics, Amer. Cancer Society, Amer. Coll. of Chest Physicians, Amer. Coll. of Preventive Medicine, Amer. Heart Association, Amer. Lung Association, Amer. Medical Association, Amer. Medical Women's Assn, Amer. Public Health Assn, Amers. for Nonsmokers' Rights, Assoc. State/Terr. Health Officials, Natl Center for Tobacco-Free Kids, National Medical Association, Onyx Group, Partnership for Prevention, Science and Public Policy Institute, Smokeless States National Program, Stop Teenage Addiction to Tobacco, Tobacco Products Liability Project.

¹² Final Report of the Advisory Committee on Tobacco Policy and Public Health, co-chair, C. Everett Koop, M.D., Sc.D. and David A. Kessler, M.D., July 1997, pp. 3-4.

- There should be *no* limitations on or special exceptions to FDA authority to regulate nicotine, other constituents, and ingredients of tobacco products and such a no-limitations policy should be made completely explicit.
- The FDA should continue to have authority to regulate further nicotine, other constituents, and ingredients as the evidence suggests. The best science, information, and health policy (and not an arbitrary deadline) should drive FDA regulatory timing and that authority should be made completely explicit.
- The FDA should have the authority to test nicotine levels by brand, based on the best science and that authority should be made completely explicit.
- Regulation of non-tobacco nicotine delivery devices (e.g., nicotine patches, nicotine gum, nicotine inhalers, etc.) should be done in a manner that does not make the development and sale of less hazardous systems difficult and that encourages maximum overall reduction in disease.¹³

Major medical and public health organizations have also individually strongly supported the FDA regulation of tobacco products. These include, for example:

1. The American Medical Association (AMA)

Official AMA policy states that: "[T]he AMA supports the regulation of tobacco products by the FDA."¹⁴ Moreover, the AMA also recently reiterated that policy in

¹³ *Ibid.*

¹⁴ AMA Policy Compendium, H-490.962 (Res. 243, A-89; Reaffirmed in lieu of Res. 232, I-94, Sub, Res. 406, I-95, Reaffirmation I-96).

its *Journal of the American Medical Association* in which after stating that: "the consequences of tobacco to the public health have been, and will continue to be, staggering, and the importance of bringing this hazard under control is correspondingly great",¹⁵ the AMA recommended, inter alia, that "[t]obacco itself should be considered a drug delivery vehicle and placed under the oversight of the Food and Drug Administration, with appropriate regulation as for other life-threatening drugs."¹⁶

2. American Cancer Society (ACS)

The American Cancer Society . . . applaud(s) Dr. David Kessler and the Clinton Administration for their courageous leadership in dealing with one of the biggest public health crises of our time. . . . We support this rule without reservation. In what will prove to be one of the most important public health measures of our time, the Food and Drug Administration has just released regulations asserting jurisdiction over tobacco for the first time.¹⁷

3. American Lung Association (ALA)

. . . . We commend the FDA for assuming jurisdiction over tobacco products through its rule to protect children.

¹⁵ Lundberg, Editor, *The Brown and Williamson Documents: Where Do We Go From Here*, 274 JAMA 256 (1995).

¹⁶ *Ibid.* p. 258 citing Lundberg GD, Tobacco for consenting adults in private only, 255 JAMA 1051-1053(1986).

¹⁷ Statement by George Dessart, Chairman of the American Cancer Society, on release of the final FDA regulations on tobacco.

... It is ludicrous that nicotine gum and nicotine replacement patches, which are designed to break the chain of tobacco addiction, are strictly regulated by the FDA, while cigarettes and smokeless tobacco products, which disable and kill hundreds of thousands of people each year, get off the regulatory hook. Today's action and request of the FDA are a continuation of the efforts that were started in 1988 when the American Lung Association, the American Heart Association and the American Cancer Society and a number of other organizations filed the first in a number of petitions with the FDA, asking the FDA to declare jurisdiction over tobacco products and to apply comparable regulatory standards to tobacco products as is applied to drugs and devices.¹⁸

4. American Public Health Association (APHA)

... The American Public Health Association (APHA) applauds the Administration's swift action that allows the FDA to regulate the sale and advertising of tobacco products to minors.

... APHA agrees with Dr. Kessler that nicotine is an addictive drug, and adds that tobacco use caused by addiction to nicotine causes 500,000 preventable deaths in the United States each year.¹⁹

¹⁸ Press Briefing, Statement of John R. Garrison, Managing Director, American Lung Association, "Petition to the Food and Drug Administration", Washington, D.C., January 15, 1998.

¹⁹ American Public Health Association, Press Release, "Regulating Adolescent's Access To Tobacco Will Reduce the Number of Children Who Begin Smoking Each Day," August 23, 1996.

5. Association of State and Territorial Health Officials (ASTHO)

... The Association of State and Territorial Health Officials (ASTHO), representing the chief public health officials in each state and U.S. territory, stated today its enthusiastic support for the Food and Drug Administration's regulations monitoring the sale and promotion of tobacco products to protect children and adolescents.²⁰

6. American College of Physicians

... The American College of Physicians, the nation's largest medical specialty society representing 89,000 internists, fully supports the action today by the President and the Food and Drug Administration to regulate tobacco as a drug delivery device. ... Tobacco addiction most often begins in children and adolescents, and statistics show that continued tobacco use is the cause of more than 400,000 deaths each year.

Tobacco-related diseases are the single most preventable cause of death, disease and disability in the United States. The nation's internists - specialists in adult medicine and the care of cancer, respiratory, and a cardiac illness - know that forceful action is essential to eliminate this epidemic.²¹

²⁰ Association of State and Territorial Health Officials, Press Release, "State Health Officials Welcome New Tobacco Regulations", Washington, D.C., August 23, 1996.

²¹ American College of Physicians, Press Release, "American College of Physicians: Regulate Tobacco" Philadelphia, PA, August 23, 1996.

II. CONFLICT OF JURISDICTIONS

ASH urges the Court to grant certiorari in this case because, in addition to its involving a matter of supreme public health importance, the instant case, *Brown and Williamson Tobacco Corp. v. Food and Drug Administration*, 153 F.3d 155 (4th Cir. 1998) from the United States Court of Appeals for the Fourth Circuit, conflicts with *Action on Smoking and Health v. Harris*, 655 F.2d 236 (1980) deciding by the United States Court of Appeals, District of Columbia Circuit. The Circuits conflict on the authority of the FDA to regulate tobacco products and the deference that the courts should give to an agency's interpretation of its own statute.

In *Action on Smoking and Health*, the U.S. Court of Appeals for the D.C. Circuit, defers to the FDA's interpretation of its statute, the FDCA, but in the instant case *Brown and Williamson Tobacco Corp. v. Food and Drug Administration*, the Fourth Circuit substitutes a de novo interpretation of the statute.

In discussing the standard of review of the FDA's action, the U.S. Court of Appeals, District of Columbia Circuit, concluded that a "deferential approach is mandated", stating in relevant part:

... ASH would have this court substitute its judgment for that of the commissioner, approaching the question of statutory interpretation de novo. We do not believe that such an approach is warranted in this case.

On the contrary, the construction and application of a statute by those charged with its administration is entitled to substantial deference. . . . [citations omitted]. This court has noted two basic rationales justifying a deferential regard for administrative interpretation of

statutes: administrative expertise and congressional acquiescence in the administrative interpretation. . . . [citations omitted] We believe that the latter basis is relevant to the consideration of the administrative interpretation at issue here and agree with the district court. . . . [citations omitted].

By contrast, in the instant case in the U.S. Court of Appeals for the Fourth Circuit, the majority refuses to defer to the agency's interpretation of its own FDCA, and instead enters into a convoluted analysis of Congressional intent despite "as much as conceding that tobacco products fit the FDA's 'literal' definition of a drug." *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d at 177.

The majority concedes that "[a] mechanical reading of only the definitions provisions may appear to support the government's position that tobacco products fit within the Act's definitions of drugs and devices. *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d at 163. Moreover, the majority had previously acknowledged that:

The FDA correctly contends that the language of the statute must be the starting point of our analysis. We agree that the first step of statutory construction is determining the plain meaning of the statutory language when the language is unambiguous and "the statutory scheme is coherent and consistent." *Robinson v. Shell Oil*, 65 U.S.L.W. 4103, 4104 (U.S. Feb. 18, 1997) (No. 95-1376) (quoting *Ron Pair Enter.*, 489 U.S. at 249, 109 S.Ct. 1026).

Nonetheless, the majority then refuses to defer to the FDA's determination that the tobacco products fit within the statutory language of the FDCA and instead embarks on an analysis of Congressional intent.

Even here, after conceding that the Court "do[es] not dispute in this case that Congress has charged the FDA with protecting the public health and that tobacco products present serious health risks for the public", *id.* at 167, the Court still refuses to defer to agency discretion. Instead the majority looks to "extrinsic evidence" to reach its conclusion "that Congress did not intend to delegate jurisdiction over tobacco products to the FDA." *Id.* at 176.

III. CONGRESSIONAL INTENT

Although ASH contends that the FDA's jurisdiction to regulate tobacco products can be upheld based on deference to the FDA's interpretation of its own statute, and there is no need to look to extrinsic information as the majority of the Fourth Circuit did, a review of Congressional intent actually supports FDA regulation of tobacco products rather than undermines it as the majority in the Fourth Circuit concluded.

A. Historical Inaction By FDA

The majority in the Fourth Circuit erroneously rely on historical inaction by the FDA and in particular the agency's refusal in *ASH v. Harris*, 656 F.2d 236 (1980), to assert its jurisdiction over tobacco products, as a basis for finding that Congress didn't intend to give the FDA authority over tobacco products. Contrary to the suggestion that *ASH v. Harris* supports the Fourth Circuit opinion, that case actually provides the foundation for the FDA's decision to regulate tobacco products now that an abundance of new information has come to light in recent years through the release of tens of thousands of previously secret tobacco industry documents, which clearly

show that tobacco products meet the statutory definition of "drugs" or "devices", 21 U.S.C. 321(g)(1)(C) and (h)(3), and that the tobacco industry has known this for years and withheld the information from the public.

For example, in one document which recently became public, Addison Yeaman, general counsel to Brown and Williamson ("B&W"), declared in a memorandum to colleagues, "Moreover, nicotine is addictive. We are, then, in the business of selling nicotine, an addictive drug effective in the release of stress mechanisms."²²

In another recently disclosed document, Claude E. Teague, Jr., an assistant director of research at R.J. Reynolds who was later promoted to an executive position stated:

In a sense, the tobacco industry may be thought of as being a *specialized, highly ritualized and stylized segment of the pharmaceutical industry. Tobacco products, uniquely, contain and deliver nicotine, a potent drug with a variety of physiological effects . . .* Thus a tobacco product is, in essence, *a vehicle for delivery of nicotine, designed to deliver the nicotine in a generally acceptable and attractive form. Our industry is then based upon design, manufacture and sale of attractive dosage forms of nicotine. . . .* (emphasis added)²³

²² Addison Yeaman, "Implications of Battelle Hippo I & II and the Griffith Filter," 1963, quoted in John Slade, et al., "Nicotine and Addiction: The Brown and Williamson Documents," J.Am.Med.Ass'n, Vol. 274, No. 3, pp. 225-33, July 19, 1995 (emphasis added).

²³ Claude E. Teague, Jr., "The Nature of the Tobacco Business and the Crucial Role of Nicotine Therein, Research Planning Memorandum," R.J. Reynolds, April 14, 1972 (Minn. trial exh. 12408).

These and over 40,000 other previously secret tobacco industry documents provided substantial new facts on which the FDA could reevaluate its decision to regulate tobacco products. As Judge Hall said in his dissent:

It is a familiar canon of administrative law that an agency can change its view of what action is possible or necessary, particularly when new facts come to light. See *Rust v. Sullivan*, 500 U.S. 173, 186-87 (1991) ("An agency . . . must be given latitude to adapt its rules and policies to the demands of changing circumstances") (citations and internal quotation marks omitted). Even when upholding the FDA's earlier denial of its own power to regulate tobacco, the court (U.S. Court of Appeals, District of Columbia Circuit) added the following caveat:

Nothing in this opinion should suggest that the [FDA] is irrevocably bound by any long-standing interpretation and representations thereof to the legislative branch. An administrative agency is clearly free to revise its interpretations. . . . The very structure of the [FDAC] which the FDA must administer, moreover, calls for case-by-case analysis. Should an agency depart from its prior interpretations, however, it must provide a reasoned explanation for its action. . . . [citations omitted]. *ASH*, 655 F.2d at 242 n.10

B. Congressional Action

Despite acknowledging "the general reluctance of courts to reply on congressional inaction as a basis for statutory interpretation, See *Brecht v. Abrahamson*, 507 U.S. 619, 632 (1993) (noting that '[a]s a general matter, "we are reluctant to draw inferences from Congress's failure to

act"') (quoting *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 306 (1988))", *Brown and Williamson Tobacco Corp. v. Food and Drug Administration*, 153 F.3d at 170, the majority of the Fourth Circuit then interprets Congress' failure to enact legislation specifically granting the FDA jurisdiction over tobacco products as legislative acquiescence in FDA's earlier decision not to regulate tobacco. Yet certainly more significant than congressional inaction during the years when the tobacco companies concealed the relevant information about the addictive properties of nicotine from Congress and the public at large, thereby providing Congress with no basis for action, is the Congressional inaction in light of the FDA regulations on tobacco currently under review.

The FDA regulations which are the subject of this case were published in the Federal Register as a proposed rule on August 11, 1995 (60 Fed. Reg. 41,314) and as final regulations on August 28, 1996 (61 Fed. Reg. 44,619) and received extensive public coverage. In addition, FDA Commissioner David A. Kessler testified several times before Congressional committees on this issue. In his widely-televised remarks, he told the members that newly-discovered evidence about the addictive nature of nicotine, and cigarette maker's knowledge of this property and their efforts to manipulate it, would force the FDA to regulate nicotine in cigarettes – as it has long regulated nicotine in other forms (e.g., in patches, chewing gum, and inhalants) if Congress declined to amend the statute. In the almost four years since this public announcement, there has been no serious Congressional attempt to remove FDA's authority to regulate tobacco products, an indication surely of legislative acquiescence not only in FDA's authority generally to regulate tobacco

products, but specifically an acceptance of the specific FDA regulations for tobacco products now before the Court.

Additionally, it is instructive to note that Congress has excluded tobacco products from other federal laws and clearly could have done so with the Food, Drug and Cosmetic Act. Federal laws which specifically excluded tobacco products, include:

1. The Federal Hazardous Substances Act

Under the heading "definitions", the Federal Hazardous Substance Act specifies that the term "hazardous substance" does not include "tobacco and tobacco products" Sec. 2(f)(2). P.L. 86-613, signed July 12, 1960.

2. Fair Packaging And Labeling Act

Under the heading "definitions", the Fair Packaging and Labeling Act specifies that the term "consumer commodity" does not include "any . . . tobacco or tobacco product" Sec. 10(a)(1), P.L. 89-755, signed November 3, 1966.

3. Consumer Product Safety Act

Under the heading "definitions", the Consumer Product Safety Act specifies that the term "consumer product" does not include "tobacco and tobacco products." Sec. 3(a)(1)(B), P.L. 92-573, signed October 27, 1972.

4. Toxic Substances Control Act

Under the heading "definitions", the Toxic Substance Control Act specifies that the term "chemical substances" does not include "tobacco or any tobacco product." Sec. 3(2)(B)(iii), P.L. 94-469, signed October 11, 1976.

Most significantly, as recently as 1994, Congress explicitly excluded tobacco from the "dietary supplements" exemption from the definitions of a "drug" in the FDCA itself.²⁴

Clearly, Congress could have excluded tobacco entirely from the coverage of the FDCA at the time. It did not. In fact, it can be argued that by excluding tobacco from the "dietary supplements" definition, Congress was expressing its intent to retain FDA jurisdiction over tobacco as a "drug".

As with the "dietary supplements" provision and the other laws in which Congress uniquely excluded tobacco products, it could have done so with the Food, Drug & Cosmetic Act. It did not. Moreover, in the years since FDA announced its intention to begin regulating tobacco products in light of the new information that it had received, Congress has made no attempt to preclude FDA regulation of tobacco. In effect, Congress has acquiesced in the FDA regulation of tobacco products. Congressional inaction supports FDA jurisdiction over tobacco products and the upholding of the current regulations rather than undermining it as the majority in the Fourth Circuit contends.

IV. CONCLUSION

Amicus Curiae, Action on Smoking and Health, supports the FDA's Petition for Writ of Certiorari. ASH urges the Court to grant the Writ. In addition to the arguments made by the FDA, ASH urges the Court to grant the Writ because of the utmost public importance of the case. Inasmuch as the tobacco products, which the FDA seeks

²⁴ Pub L. No. 103-407, sec. 2(a), 108 Stat. 4325, 4327 (codified at 21 U.S.C. sec. 321(ff)(1)).

to regulate, are the leading preventable cause of death in the United States, killing over 400,000 people a year, a decision in this case will have major public health ramifications well into the next millennium. It will also have a major impact on the U.S. economy due to the billions of dollars of health care and other costs related to smoking.

Additionally, ASH urges the Court to hear this case because the decision of the Fourth Circuit in the instant case conflicts with the United States Court of Appeals, District of Columbia Circuit, regarding the deference that courts should give to the FDA's interpretation of its own FDCA and, in particular, its authority to regulate tobacco products. Further, in refusing to defer to agency discretion, the Fourth Circuit presents an incomplete and convoluted analysis of Congressional intent, which, if left to stand, could seriously undermine the FDA's ability to regulate other "drugs" and "devices" which put the public at serious risk of death and disease.

Respectfully submitted,

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(12)
No. 98-1152

In the Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, ET AL.,
PETITIONERS

v.

BROWN AND WILLIAMSON TOBACCO CORP., ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

JOINT APPENDIX

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PETITION FOR WRIT OF CERTIORARI FILED: JANUARY 19, 1999
CERTIORARI GRANTED: APRIL 26, 1999

6799

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UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA
(GREENSBORO)

Civil No. 95-CV-591

COYNE BEAHM, INC., BROWN & WILLIAMSON
TOBACCO CORPORATION, LIGGETT GROUP, INC.,
LORILLARD TOBACCO COMPANY, PHILIP MORRIS,
INCORPORATED, R. J. REYNOLDS TOBACCO COMPANY,
PLAINTIFFS

v.

UNITED STATES FOOD & DRUG ADMINISTRATION,
DAVID A. KESSLER, M.D., COMMISSIONER OF
FOOD AND DRUGS, DEFENDANTS

DOCKET ENTRIES

<u>DATE</u>	<u>DOCKET NUMBERS</u>	<u>PROCEEDINGS</u>
		* * * * *
8/23/96	27	MOTION by COYNE BEAHM, INC., BROWN & WILLIAM- SON, LIGGETT GROUP, INC., LORILLARD TOBACCO CO, MORRIS, PHILIP, INC., REYNOLDS, R. J., TOB for Leave to File Second Amended Complaint w/pro- posed Second Amended Com

DATE	DOCKET NUMBERS	PROCEEDINGS
		plaint attached. (ww) [Entry date 08/26/96]
		* * * * *
10/1/96	34	ANSWER by US FOOD & DRUG ADMIN, DAVID A. KESSLER to second amended complaint (ww) [Entry date 10/02/96]
		* * * * *
10/15/96	36	MOTION FOR SUMMARY JUDGMENT by plaintiff COYNE BEAHM, INC., plain- tiff BROWN & WILLIAMSON, plaintiff LORILLARD TO- BACCO CO, plaintiff MORRIS, PHILIP, INC., plaintiff REY- NOLDS, R. J., TOB (rh)
		* * * * *
2/10/97	—	Motion hearing held before Jd. Osteen, G'boro. Beck Rptr. re: [36-1] motion FOR SUM- MARY JUDGMENT by REY- NOLDS, R. J., TOB, MORRIS, PHILIP, INC., LORILLARD TOBACCO CO, BROWN

DATE	DOCKET NUMBERS	PROCEEDINGS
		& WILLIAMSON, COYNE BEAHM, INC., Ct will enter findings in 5-10 weeks. (jm) [Entry date 02/11/97]
		* * * * *
4/25/97	70	MEMORANDUM OPINION (signed by Judge William L. Osteen Sr.) Re: [36-1] motion for summary judgment. Ccs. to counsel. (cg)
4/25/97	71	ORDER (signed by Judge William L. Osteen Sr.) [36-1] motion for summary judgment is granted as to the regula- tions' restrictions on the pro- motion and advertising of tobacco products and denied as to the Regulations access restrictions and labeling re- quirements. An immediate appeal from this order may materially advance the ulti- mate termination of the litiga- tion. Therefore the court cer- tifies this order for an inter- locutory appeal purs. to 28 USC 1292(b). The Regula

DATE	DOCKET NUMBERS	PROCEEDINGS
		tions heretofore implemented prohibiting the sale of tobacco products to minors shall remain in full force and effect pending appeal by pltfs. The Food and Drug Administration shall not implement any of the additional Regulations set for implementation on 8/28/97, pending further orders by the court. Nothing set forth in this order concerning the time of implementation of the Regulations shall prohibit either side from presenting motions to the court for a reconsideration as to the implementation of the regulations pending appeal. Further ordered that absent a timely appeal or absent permission of the Court of Appeals for the Fourth Circuit to proceed with an interlocutory appeal, this matter shall proceed for ultimate disposition by the court. Ccs. to counsel. (cg) [Edit date 04/25/97]

DATE	DOCKET NUMBERS	PROCEEDINGS
5/2/97	72	NOTICE OF APPEAL from order entered 4/25/97 to USCA 4th Circuit by US FOOD & DRUG ADMIN, DAVID A. KESSLER. (rh) * * * * *

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA
(GREENSBORO)

Civil No. 95-CV-593

AMERICAN ADVERTISING FEDERATION,
AMERICAN ASSOCIATION OF ADVERTISING AGENCIES,
ASSOCIATION OF NATIONAL ADVERTISERS, INC.,
MAGAZINE PUBLISHERS OF AMERICA,
OUTDOOR ADVERTISING ASSOCIATION OF AMERICA,
POINT OF PURCHASE ADVERTISING INSTITUTE,
PLAINTIFFS

v.

DAVID A. KESSLER, M.D., COMMISSIONER,
FOOD AND DRUG ADMINISTRATION, UNITED STATES
UNITED STATES FOOD & DRUG ADMINISTRATION,
DEFENDANTS

DOCKET ENTRIES

DATE	DOCKET NUMBERS	PROCEEDINGS
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9/16/96	39	SECOND AMENDED COMPLAINT by AMERICAN ADVERTISING, AMERICAN ASSOCIATION, ASSN. OF NATL. ADVT., MAGAZINE PUBLISHERS, OUTDOOR AD

DATE	DOCKET NUMBERS	PROCEEDINGS
		VERTISING, POINT OF PURCHASE amending [1-1] complaint (kd) [Entry date 09/19/96]
* * * * *		
10/1/96	41	ANSWER by DAVID A. KESSLER, US FOOD & DRUG ADMIN to second amended complaint. (kd) [Entry date 10/02/96]
* * * * *		
10/15/96	45	MOTION FOR SUMMARY JUDGMENT by plaintiff AMERICAN ADVERTISING, plaintiff AMERICAN ASSOCIATION, plaintiff ASSN. OF NATL. ADVT., plaintiff MAGAZINE PUBLISHERS, plaintiff OUTDOOR ADVERTISING, plaintiff POINT OF PURCHASE (kd) [Entry date 10/16/96]
* * * * *		
2/10/97	—	Motion hearing held before Jd. Osteen, G'boro. Beck Rptr.

<u>DATE</u>	<u>DOCKET NUMBERS</u>	<u>PROCEEDINGS</u>
		re: [45-1] motion FOR SUMMARY JUDGMENT by plaintiffs. Ct will enter findings in 5-10 weeks. (jm) [Entry date 02/11/97]
		* * * * *
4/25/97	66	MEMORANDUM OPINION (copy - original filed in 2:95CV591) (signed by Judge William L. Osteen Sr.) [45-1] motion for summary judgment. Ccs. to counsel. (cg)
4/25/97	67	ORDER (copy - original filed in 2:95CV591) (signed by Judge William L. Osteen Sr.) [45-1] motion for summary judgment is granted as to the Regulations' restrictions on the promotion and advertising of tobacco products and denied as to the Regulations access restrictions and labeling requirements. An immediate from this order may materially advance the ultimate termination of the litigation. Therefore, the court

<u>DATE</u>	<u>DOCKET NUMBERS</u>	<u>PROCEEDINGS</u>
		certifies this order for an interlocutory appeal purs. to 28 USC 1292(b). The Regulations heretofore implemented prohibiting the sale of tobacco products to minors shall remain in full force and effect pending appeal by pltfs. The Food and Drug Administration shall not implement any of the additional Regulations set for implementation on 8/28/97, pending further orders by the court. Nothing set forth in this order concerning the time of implementation of the Regulations shall prohibit either side from presenting motions to the court for a reconsideration as to the implementation of the Regulations pending appeal. Further ordered that absent a timely appeal or absent permission of the Court of Appeals for the Fourth Circuit to proceed with an interlocutory appeal, this matter shall proceed for ultimate disposition by the court. Ccs. to counsel. (cg) [Edit date 04/25/97]

DATE	DOCKET NUMBERS	PROCEEDINGS
5/2/97	68	NOTICE OF APPEAL from order entered 4/25/97 (copy- original filed in 2:95CV591) to USCA 4th Circuit by DAVID A. KESSLER, US FOOD & DRUG ADMIN (rh)

* * * * *

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA
(WINSTON-SALEM)

Civil No. 95-CV-665

UNITED STATES TOBACCO COMPANY, BROWN &
WILLIAMSON TOBACCO CORPORATION, CONWOOD
COMPANY, L.P., NATIONAL TOBACCO COMPANY, L.P.,
THE PINKERTON TOBACCO COMPANY, SWISHER
INTERNATIONAL, INC., CENTRAL CAROLINA GROCERS,
INC., J. T. DAVENPORT, INC., N. C. TOBACCO
DISTRIBUTORS COMMITTEE, INC., PLAINTIFFS

v.

UNITED STATES FOOD & DRUG ADMINISTRATION,
DAVID A. KESSLER, M.D., COMMISSIONER OF FOOD
AND DRUGS, DEFENDANTS

DOCKET ENTRIES

DATE	DOCKET NUMBERS	PROCEEDINGS
8/23/96	21	FIRST AMENDED COM- PLAINT by ALL PLAIN- TIFFS amending [1-1] com- plaint (cmh) [Entry date 08/26/96]

* * * * *

* * * * *

<u>DATE</u>	<u>DOCKET NUMBERS</u>	<u>PROCEEDINGS</u>
10/1/96	25	ANSWER by US FOOD & DRUG ADMIN, DAVID A. KESSLER to amended complaint (cmh) [Entry date 10/02/96]
		* * * * *
10/15/96	27	MOTION For Summary Judg- ment invalidating and per- manently enjoining enforce- ment of the FDA Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to protect Children and Adolescents by ALL PLAINTIFFS. (cmh)
		* * * * *
2/10/97	—	Motion hearing held before Jd. Osteen, G'boro. Beck Rptr. re: [27-1] motion For Sum- mary Judgment invalidating and permanently enjoining enforcement of the FDA Regulations Restricting the Sale and Distribution of Ciga- rettes and Smokeless Tobacco to protect Children and Ado- lescents by ALL PLAIN-

<u>DATE</u>	<u>DOCKET NUMBERS</u>	<u>PROCEEDINGS</u>
		TIFFS. Ct will enter findings in 5-10 weeks. (jm) [Entry date 02/11/97]
		* * * * *
4/25/97	60	MEMORANDUM OPINION (copy - original filed in 2:95CV591) (signed by Judge William L. Osteen Sr.) Re: [27-1] motion for summary judgment. Ccs. to counsel. (cg)
4/25/97	61	ORDER (copy - original filed in 2:95CV591) (signed by Judge William L. Osteen Sr.) [27-1] motion for summary judgment is granted as to the Regulations restrictions on the promotion and advertising of tobacco products and de- nied as to the Regulations Ac- cess restrictions and labeling requirements. An immediate appeal from this order may materially advance the ulti- mate termination of the litiga- tion. Therefore, the court certifies this order for an interlocutory appeal purs. to

<u>DATE</u>	<u>DOCKET NUMBERS</u>	<u>PROCEEDINGS</u>
		<p>28 USC 1292(b). The Regulations heretofore implemented prohibiting the sale of tobacco products to minors shall remain in full force and effect pending appeal by pltfs. The Food and Drug Administration shall not implement any of the additional Regulations set for implementation on 8/28/97, pending further orders by the court. Nothing set forth in this order concerning the time of implementation of the Regulations shall prohibit either side from presenting motions to the court for a reconsideration as to the implementaion of the regulations pending appeal. Further ordered that adsent a timely appeal or absent permission of the Court of Appeals for the Fourth Circuit to proceed with an interlocutory appeal, this matter shall proceed for ultimate disposition by the court. Ccs. to counsel. (cg)</p>

<u>DATE</u>	<u>DOCKET NUMBERS</u>	<u>PROCEEDINGS</u>
5/2/97	62	<p>NOTICE OF APPEAL from order entered 4/25/97 (copy-original filed in 2:95CV591) to USCA 4th Circuit by US FOOD & DRUG ADMIN, DAVID A. KESSLER (rh)</p>

* * * * *

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA
(GREENSBORO)

Civil No. 95-CV-706

NATIONAL ASSOCIATION OF CONVENIENCE STORES,
ACME RETAIL, INC., PLAINTIFFS

v.

DAVID A. KESSLER, M.D., COMMISSIONER, FOOD
AND DRUG ADMINISTRATION, UNITED STATES FOOD
& DRUG ADMINISTRATION, DEFENDANTS

DOCKET ENTRIES

DATE	DOCKET NUMBERS	PROCEEDINGS
* * * * *		
8/30/96	13	FIRST AMENDED COMPLAINT by NATL. ASSN. CONV., ACME RETAIL, INC. amending [1-1] complaint. (cmh)
* * * * *		
10/1/96	17	ANSWER by DAVID A. KESSLER, US FOOD & DRUG ADMIN to amended complaint (cmh) [Entry date 10/02/96]

DATE	DOCKET NUMBERS	PROCEEDINGS
* * * * *		
10/15/96	20	MOTION For Summary Judgment invalidating and permanently enjoining enforcement of the FDA Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco by plaintiff NATL. ASSN. CONV., plaintiff ACME RETAIL, INC. (cmh) [Entry date 10/16/96]
* * * * *		
2/10/97	—	Motion hearing held before Jd. Osteen, G'boro. Beck Rptr. re: [20-1] motion For Summary Judgment invalidating and permanently enjoining enforcement of the FDA Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco by ACME RETAIL, INC., NATL. ASSN. CONV. Ct will enter findings in 5-10 weeks. (jm) [Entry date 02/11/97]
* * * * *		

<u>DATE</u>	<u>DOCKET NUMBERS</u>	<u>PROCEEDINGS</u>
4/25/97	52	MEMORANDUM OPINION (copy - original filed in 2:95CV591) (signed by Judge William L. Osteen Sr.) Re: [20-1] motion for summary judgment. Ccs. to counsel. (cg)
4/25/97	53	ORDER (copy - original filed in 2:95CV591) (signed by William L. Osteen Sr.) [20-1] motion for summary judgment is granted as to the Regulations restrictions on the promotion and advertising of tobacco products and denied as to the Regulations access restrictions and labeling requirements. An immediate appeal from this order may materially advance the ultimate termination of the litigation. Therefore, the court certifies this order for an interlocutory appeal purs. to 28 USC 1292(b). The Regulations heretofore implemented prohibiting the sale of tobacco products to minors shall remain in full force and effect

<u>DATE</u>	<u>DOCKET NUMBERS</u>	<u>PROCEEDINGS</u>
		pending appeal by pltfs. The Food and Drug Administration shall not implement any of the additional Regulations set for implementation on 8/28/97, pending further orders by the court. Nothing set forth in this order concerning the time of implementation of the Regulations shall prohibit either side from presenting motions to the court for a reconsideration as to the implementation of the regulations pending appeal. Further ordered that absent a timely appeal or absent permission of the Court of Appeals for the Fourth Circuit to proceed with an interlocutory appeal, this matter shall proceed for ultimate disposition by the court. Ccs. to counsel. (cg)

<u>DATE</u>	<u>DOCKET NUMBERS</u>	<u>PROCEEDINGS</u>
5/2/97	54	NOTICE OF APPEAL from order entered 4/25/97 (copy- original filed in 2:95CV591) to USCA 4th Circuit by DAVID A. KESSLER, US FOOD & DRUG ADMIN (rh)

* * * * *

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 97-1581

COYNE BEAHM, INCORPORATED, BROWN &
WILLIAMSON TOBACCO CORPORATION, PHILIP MORRIS,
INCORPORATED, R. J. REYNOLDS TOBACCO COMPANY,
NATIONAL ASSOCIATION OF CONVENIENCE STORES,
ACME RETAIL INCORPORATED, UNITED STATES
TOBACCO COMPANY, CONWOOD COMPANY, L.P.,
NATIONAL TOBACCO COMPANY, L.P., PINKERTON
TOBACCO COMPANY,
SWISHER INTERNATIONAL, INCORPORATED, CENTRAL
CAROLINA GROCERS, INCORPORATED, J. T.
DAVENPORT, INCORPORATED, NORTH CAROLINA
TOBACCO DISTRIBUTORS COMMITTEE, INCORPORATED,
THE AMERICAN ADVERTISING FEDERATION,
AMERICAN ASSOCIATION OF ADVERTISING AGENCIES,
ASSOCIATION OF NATIONAL ADVERTISERS,
INCORPORATED, MAGAZINE PUBLISHERS OF AMERICA,
THE OUTDOOR ADVERTISING ASSOCIATION OF
AMERICA, INCORPORATED, POINT OF PURCHASE
ADVERTISING INSTITUTE, LORILLARD TOBACCO
COMPANY, PLAINTIFFS-APPELLEES
AND
LIGGETT GROUP, INCORPORATED, PLAINTIFF

v.

FOOD & DRUG ADMINISTRATION,
DAVID A. KESSLER, M.D., COMMISSIONER OF FOOD
AND DRUGS, DEFENDANTS-APPELLANTS

DOCKET ENTRIES

DATE	PROCEEDINGS
* * * * *	
8/11/97	Oral argument heard. Courtroom Deputy: Richard Sewell, Joseph Coleman, Diane Burke. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (psc) [97-1581 97-1604 97-1605 97-1606 97-1614]
4/16/98	COURT ORDER filed for reargument of appeal [2754116-1] Copies to all counsel. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
* * * * *	
6/9/98	Oral argument heard. Courtroom Deputy: JLC, DHB, RHS. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (rhs) [97-1581 97-1604 97-1605 97-1606 97-1614]
* * * * *	
8/14/98	Published, authored opinion filed. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (mst) [97-1581 97-1604 97-1605 97-1606 97-1614]
8/14/98	Judgment order filed. Decision: REVERSED. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (mst) [97-1581 97-1604 97-1605 97-1606 97-1614]

DATE	PROCEEDINGS
9/25/98	Petition filed by Appellee FDA in 97-1604, Appellee David A. Kessler in 97-1604, Appellant FDA in 97-1581, Appellant David A. Kessler in 97-1581, Appellee FDA in 97-1605, Appellee David A. Kessler in 97-1605, Appellant FDA in 97-1606, Appellant David A. Kessler in 97-1606, Appellee David A. Kessler in 97-1614, Appellee FDA in 97-1614 for rehearing. Number copies filed: 20 [2851942-1]., for suggestion for rehearing in banc. Number of copies filed: 20 [2851942-2]. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
* * * * *	
11/10/98	PUBLISHED COURT ORDER filed denying motion for rehearing [2851942-1] in 97-1614, 97-1581, 97-1605, 97-1606, 97-1614, denying motion for suggestion for reh in banc [2851942-2] in 97-1614, 97-1581, 97-1605, 97-1606, 97-1614 Copies to all counsel. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
11/16/98	Motion filed by Appellee FDA, et al in 97-1604, Appellant FDA, et al in 97-1581, Appellee FDA, et al. in 97-1605, Appellant FDA, et al. in 97-1606, Appellee FDA, et al. in 97-1614 to stay the mandate

<u>DATE</u>	<u>PROCEEDINGS</u>
	[2882616-1]. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
11/18/98	COURT ORDER filed granting motion to stay mandate [2882616-1] until for a period of 30 days from the date of the filing of this order pending the filing of a petition for certiorari by the government. Judge Hall dissented. 97-1604, 97-1581, 97-1605, 97-1606, 97-1614 Copies to all counsel. [97-1604, 97-1581, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
12/14/98	Motion filed by Appellee FDA in 97-1604, Appellee David A. Kessler in 97-1604, Appellant FDA in 97-1581, Appellant David A. Kessler in 97-1581, Appellee FDA in 97-1605, Appellee David A. Kessler in 97-1605, Appellant FDA in 97-1606, Appellant David A. Kessler in 97-1606, Appellee David A. Kessler in 97-1614, Appellee FDA in 97-1614 to stay the mandate [898734-1]. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (mst) [97-1581 97-1604 97-1605 97-1606 97-1614]

<u>DATE</u>	<u>PROCEEDINGS</u>
12/17/98	COURT ORDER filed granting motion to stay mandate [2898734-1] until January 18, 1999 in 97-1604, 97-1581, 97-1605, 97-1606, 97-1614 Copies to all counsel. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]

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UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 97-1604

BROWN & WILLIAMSON TOBACCO CORPORATION,
LORILLARD TOBACCO COMPANY, PHILIP MORRIS,
INCORPORATED, R. J. REYNOLDS TOBACCO COMPANY,
PLAINTIFFS-APPELLANTS

AND

COYNE BEAHM, INCORPORATED, LIGGETT GROUP,
INCORPORATED, PLAINTIFFS

v.

FOOD & DRUG ADMINISTRATION,
DAVID A. KESSLER, M.D., COMMISSIONER OF FOOD
AND DRUGS, DEFENDANTS-APPELLEES

DOCKET ENTRIES

DATE	PROCEEDINGS
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* * * * *

8/11/97	Oral argument heard. Courtroom Deputy: Richard Sewell, Joseph Coleman, Diane Burke. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (psc) [97-1581 97-1604 97-1605 97-1606 97-1614]
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DATE	PROCEEDINGS
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4/16/98	COURT ORDER filed for reargument of appeal [2754116-1] Copies to all counsel. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
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* * * * *

6/9/98	Oral argument heard. Courtroom Deputy: JLC, DHB, RHS. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (rhs) [97-1581 97-1604 97-1605 97-1606 97-1614]
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8/14/98	Published, authored opinion filed. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (mst) [97-1581 97-1604 97-1605 97-1606 97-1614]
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8/14/98	Judgment order filed. Decision: REVERSED. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (mst) [97-1581 97-1604 97-1605 97-1606 97-1614]
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9/25/98	Petition filed by Appellee FDA in 97-1604, Appellee David A. Kessler in 97-1604,
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DATE	PROCEEDINGS
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Appellant FDA in 97-1581, Appellant David A. Kessler in 97-1581, Appellee FDA in 97-1605, Appellee David A. Kessler in 97-1605, Appellant FDA in 97-1606, Appellant David A. Kessler in 97-1606, Appellee David A. Kessler in 97-1614, Appellee FDA in 97-1614 for rehearing. Number copies filed: 20 [2851942-1], for suggestion for rehearing in banc. Number of copies filed: 20 [2851942-2]. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]

* * * * *

11/10/98	PUBLISHED COURT ORDER filed denying motion for rehearing [2851942-1] in 97-1614, 97-1581, 97-1605, 97-1606, 97-1614, denying motion for suggestion for reh in banc [2851942-2] in 97-1614, 97-1581, 97-1605, 97-1606, 97-1614 Copies to all counsel. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
11/16/98	Motion filed by Appellee FDA, et al in 97-1604, Appellant FDA, et al in 97-1581, Appellee FDA, et al. in 97-1605, Appellant FDA, et al. in 97-1606, Appellee FDA, et al. in 97-1614 to stay the mandate [2882616-1].

DATE	PROCEEDINGS
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	[97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
11/18/98	COURT ORDER filed granting motion to stay mandate [2882616-1] until for a period of 30 days from the date of the filing of this order pending the filing of a petition for certiorari by the government. Judge Hall dissented. 97-1604, 97-1581, 97-1605, 97-1606, 97-1614 Copies to all counsel. [97-1604, 97-1581, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
12/14/98	Motion filed by Appellee FDA in 97-1604, Appellee David A. Kessler in 97-1604, Appellant FDA in 97-1581, Appellant David A. Kessler in 97-1581, Appellee FDA in 97-1605, Appellee David A. Kessler in 97-1605, Appellant FDA in 97-1606, Appellant David A. Kessler in 97-1606, Appellee David A. Kessler in 97-1614, Appellee FDA in 97-1614 to stay the mandate [2898734-1]. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (mst) [97-1581 97-1604 97-1605 97-1606 97-1614]
12/17/98	COURT ORDER filed granting motion to stay mandate [2898734-1] until January 18,

<u>DATE</u>	<u>PROCEEDINGS</u>
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1999 in 97-1604, 97-1581, 97-1605, 97-1606,
97-1614 Copies to all counsel. [97-1604, 97-
1581, 97-1605, 97-1606, 97-1614] (dhb) [97-
1581 97-1604 97-1605 97-1606 97-1614]

* * * * *

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 97-1605

UNITED STATES TOBACCO COMPANY, BROWN &
WILLIAMSON TOBACCO CORPORATION, CONWOOD
COMPANY, L.P., NATIONAL TOBACCO COMPANY, L.P.,
PINKERTON TOBACCO COMPANY, SWISHER
INTERNATIONAL, INCORPORATED, CENTRAL CAROLINA
GROCERS, INCORPORATED, J. T. DAVENPORT,
INCORPORATED, NORTH CAROLINA TOBACCO
DISTRIBUTORS COMMITTEE, INCORPORATED,
PLAINTIFFS-APPELLANTS

v.

FOOD & DRUG ADMINISTRATION,
DAVID A. KESSLER, M.D., COMMISSIONER OF FOOD
AND DRUGS, DEFENDANTS-APPELLEES

DOCKET ENTRIES

<u>DATE</u>	<u>PROCEEDINGS</u>
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* * * * *

8/11/97	Oral argument heard. Courtroom Deputy: Richard Sewell, Joseph Coleman, Diane Burke. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (psc) [97-1581 97-1604 97-1605 97- 1606 97-1614]
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4/16/98 COURT ORDER filed for reargument of appeal [2754116-1] Copies to all counsel. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]

* * * * *

6/9/98 Oral argument heard. Courtroom Deputy: JLC, DHB, RHS. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (rhs) [97-1581 97-1604 97-1605 97-1606 97-1614]

* * * * *

8/14/98 Published, authored opinion filed. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (mst) [97-1581 97-1604 97-1605 97-1606 97-1614]

8/14/98 Judgment order filed. Decision: REVERSED. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (mst) [97-1581 97-1604 97-1605 97-1606 97-1614]

9/25/98 Petition filed by Appellee FDA in 97-1604, Appellee David A. Kessler in 97-1604, Appellant FDA in 97-1581, Appellant David A. Kessler in 97-1581, Appellee FDA in 97-1605, Appellee David A. Kessler in 97-1605, Appellant FDA in 97-1606, Appellant David A. Kessler in 97-1606, Appellee David A. Kessler in 97-1614, Appellee FDA in 97-1614 for rehearing. Number copies filed: 20 [2851942-1]., for

DATE

PROCEEDINGS

suggestion for rehearing in banc. Number of copies filed: 20 [2851942-2]. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]

* * * * *

11/10/98 PUBLISHED COURT ORDER filed denying motion for rehearing [2851942-1] in 97-1614, 97-1581, 97-1605, 97-1606, 97-1614, denying motion for suggestion for reh in banc [2851942-2] in 97-1614, 97-1581, 97-1605, 97-1606, 97-1614 Copies to all counsel. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]

11/16/98 Motion filed by Appellee FDA, et al in 97-1604, Appellant FDA, et al in 97-1581, Appellee FDA, et al. in 97-1605, Appellant FDA, et al. in 97-1606, Appellee FDA, et al. in 97-1614 to stay the mandate [2882616-1]. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]

11/18/98 COURT ORDER filed granting motion to stay mandate [2882616-1] until for a period of 30 days from the date of the filing of this order pending the filing of a petition for certiorari by the government.

<u>DATE</u>	<u>PROCEEDINGS</u>
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Judge Hall dissented. 97-1604, 97-1581, 97-1605, 97-1606, 97-1614 Copies to all counsel. [97-1604, 97-1581, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]

12/14/98 Motion filed by Appellee FDA in 97-1604, Appellee David A. Kessler in 97-1604, Appellant FDA in 97-1581, Appellant David A. Kessler in 97-1581, Appellee FDA in 97-1605, Appellee David A. Kessler in 97-1605, Appellant FDA in 97-1606, Appellant David A. Kessler in 97-1606, Appellee David A. Kessler in 97-1614, Appellee FDA in 97-1614 to stay the mandate [2898734-1]. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (mst) [97-1581 97-1604 97-1605 97-1606 97-1614]

12/17/98 COURT ORDER filed granting motion to stay mandate [2898734-1] until January 18, 1999 in 97-1604, 97-1581, 97-1605, 97-1606, 97-1614 Copies to all counsel. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]

* * * * *

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 97-1606

COYNE BEAHM, INCORPORATED, BROWN &
WILLIAMSON TOBACCO CORPORATION, LORILLARD
TOBACCO COMPANY, PHILIP MORRIS, INCORPORATED,
R. J. REYNOLDS TOBACCO COMPANY, UNITED STATES
TOBACCO COMPANY, CONWOOD COMPANY, L.P.,
NATIONAL TOBACCO COMPANY, L.P., PINKERTON
TOBACCO COMPANY, SWISHER INTERNATIONAL,
INCORPORATED, CENTRAL CAROLINA GROCERS,
INCORPORATED, J. T. DAVENPORT, INCORPORATED,
NORTH CAROLINA TOBACCO DISTRIBUTORS
COMMITTEE, INCORPORATED, THE AMERICAN
ADVERTISING FEDERATION, AMERICAN ASSOCIATION
OF ADVERTISING AGENCIES, ASSOCIATION OF
NATIONAL ADVERTISERS, INCORPORATED, MAGAZINE
PUBLISHERS OF AMERICA, THE OUTDOOR ADVERTISING
ASSOCIATION OF AMERICA, INCORPORATED, POINT OF
PURCHASE ADVERTISING INSTITUTE, NATIONAL
ASSOCIATION OF CONVENIENCE STORES, ACME
RETAIL, INCORPORATED, LIGGETT GROUP,
INCORPORATED, PLAINTIFFS-APPELLEES

v.

FOOD & DRUG ADMINISTRATION,
DAVID A. KESSLER, M.D., COMMISSIONER OF FOOD
AND DRUGS, DEFENDANTS-APPELLANTS

DOCKET ENTRIES

DATE	PROCEEDINGS
* * * * *	
8/11/97	Oral argument heard. Courtroom Deputy: Richard Sewell, Joseph Coleman, Diane Burke. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (psc) [97-1581 97-1604 97-1605 97-1606 97-1614]
4/16/98	COURT ORDER filed for reargument of appeal [2754116-1] Copies to all counsel. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
* * * * *	
6/9/98	Oral argument heard. Courtroom Deputy: JLC, DHB, RHS. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (rhs) [97-1581 97-1604 97-1605 97-1606 97-1614]
* * * * *	
8/14/98	Published, authored opinion filed. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (mst) [97-1581 97-1604 97-1605 97-1606 97-1614]
8/14/98	Judgment order filed. Decision: REVERSED. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (mst) [97-1581 97-1604 97-1605 97-1606 97-1614]

DATE	PROCEEDINGS
9/25/98	Petition filed by Appellee FDA in 97-1604, Appellee David A. Kessler in 97-1604, Appellant FDA in 97-1581, Appellant David A. Kessler in 97-1581, Appellee FDA in 97-1605, Appellee David A. Kessler in 97-1605, Appellant FDA in 97-1606, Appellant David A. Kessler in 97-1606, Appellee David A. Kessler in 97-1614, Appellee FDA in 97-1614 for rehearing. Number copies filed: 20 [2851942-1], for suggestion for rehearing in banc. Number of copies filed: 20 [2851942-2]. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
* * * * *	
11/10/98	PUBLISHED COURT ORDER filed denying motion for rehearing [2851942-1] in 97-1614, 97-1581, 97-1605, 97-1606, 97-1614, denying motion for suggestion for reh in banc [2851942-2] in 97-1614, 97-1581, 97-1605, 97-1606, 97-1614 Copies to all counsel. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
11/16/98	Motion filed by Appellee FDA, et al in 97-1604, Appellant FDA, et al in 97-1581, Appellee FDA, et al. in 97-1605, Appellant FDA, et al. in 97-1606, Appellee FDA, et al.

<u>DATE</u>	<u>PROCEEDINGS</u>
	in 97-1614 to stay the mandate [2882616-1]. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
11/18/98	COURT ORDER filed granting motion to stay mandate [2882616-1] until for a period of 30 days from the date of the filing of this order pending the filing of a petition for certiorari by the government. Judge Hall dissented. 97-1604, 97-1581, 97-1605, 97-1606, 97-1614 Copies to all counsel. [97-1604, 97-1581, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
12/14/98	Motion filed by Appellee FDA in 97-1604, Appellee David A. Kessler in 97-1604, Appellant FDA in 97-1581, Appellant David A. Kessler in 97-1581, Appellee FDA in 97-1605, Appellee David A. Kessler in 97-1605, Appellant FDA in 97-1606, Appellant David A. Kessler in 97-1606, Appellee David A. Kessler in 97-1614, Appellee FDA in 97-1614 to stay the mandate [2898734-1]. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (mst) [97-1581 97-1604 97-1605 97-1606 97-1614]

<u>DATE</u>	<u>PROCEEDINGS</u>
12/17/98	COURT ORDER filed granting motion to stay mandate [2898734-1] until January 18, 1999 in 97-1604, 97-1581, 97-1605, 97-1606, 97-1614 Copies to all counsel. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]

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UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 97-1614

NATIONAL ASSOCIATION OF CONVENIENCE STORES,
ACME RETAIL, INCORPORATED,
PLAINTIFFS-APPELLANTS

v.

DAVID A. KESSLER, COMMISSIONER OF THE
FOOD & DRUG ADMINISTRATION,
FOOD & DRUG ADMINISTRATION,
DEFENDANTS-APPELLEES

DOCKET ENTRIES

DATE	PROCEEDINGS
* * * * *	
8/11/97	Oral argument heard. Courtroom Deputy: Richard Sewell, Joseph Coleman, Diane Burke. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (psc) [97-1581 97-1604 97-1605 97-1606 97-1614]
4/16/98	COURT ORDER filed for reargument of appeal [2754116-1] Copies to all counsel. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]

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DATE	PROCEEDINGS
6/9/98	Oral argument heard. Courtroom Deputy: JLC, DHB, RHS. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (rhs) [97-1581 97-1604 97-1605 97-1606 97-1614]
* * * * *	
8/14/98	Published, authored opinion filed. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (mst) [97-1581 97-1604 97-1605 97-1606 97-1614]
8/14/98	Judgment order filed. Decision: REVERSED. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (mst) [97-1581 97-1604 97-1605 97-1606 97-1614]
9/25/98	Petition filed by Appellee FDA in 97-1604, Appellee David A. Kessler in 97-1604, Appellant FDA in 97-1581, Appellant David A. Kessler in 97-1581, Appellee FDA in 97-1605, Appellee David A. Kessler in 97-1605, Appellant FDA in 97-1606, Appellant David A. Kessler in 97-1606, Appellee David A. Kessler in 97-1614, Appellee FDA in 97-1614 for rehearing. Number copies filed: 20 [2851942-1], for suggestion for rehearing in banc. Number of copies filed: 20 [2851942-2]. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]

DATE	PROCEEDINGS
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11/10/98 PUBLISHED COURT ORDER filed denying motion for rehearing [2851942-1] in 97-1614, 97-1581, 97-1605, 97-1606, 97-1614, denying motion for suggestion for reh in banc [2851942-2] in 97-1614, 97-1581, 97-1605, 97-1606, 97-1614 Copies to all counsel. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]

11/16/98 Motion filed by Appellee FDA, et al in 97-1604, Appellant FDA, et al in 97-1581, Appellee FDA, et al. in 97-1605, Appellant FDA, et al. in 97-1606, Appellee FDA, et al. in 97-1614 to stay the mandate [2882616-1]. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]

11/18/98 COURT ORDER filed granting motion to stay mandate [2882616-1] until for a period of 30 days from the date of the filing of this order pending the filing of a petition for certiorari by the government. Judge Hall dissented. 97-1604, 97-1581, 97-1605, 97-1606, 97-1614 Copies to all counsel. [97-1604, 97-1581, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]

DATE	PROCEEDINGS
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12/14/98 Motion filed by Appellee FDA in 97-1604, Appellee David A. Kessler in 97-1604, Appellant FDA in 97-1581, Appellant David A. Kessler in 97-1581, Appellee FDA in 97-1605, Appellee David A. Kessler in 97-1605, Appellant FDA in 97-1606, Appellant David A. Kessler in 97-1606, Appellee David A. Kessler in 97-1614, Appellee FDA in 97-1614 to stay the mandate [2898734-1]. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (mst) [97-1581 97-1604 97-1605 97-1606 97-1614]

12/17/98 COURT ORDER filed granting motion to stay mandate [2898734-1] until January 18, 1999 in 97-1604, 97-1581, 97-1605, 97-1606, 97-1614 Copies to all counsel. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]

* * * * *

[SEAL OMITTED]

Department of Health Education and Welfare
Public Health Service
Food and Drug Administration
Rockville, Maryland 20452

December 05, 1997

Mr. John F. Banzhaf, III
Executive Director and General Counsel
Action on Smoking and Health
2000 H Street, N.W.
Washington, D.C. 20006

Dear Mr. Banzhaf:

This is in reply to your petition dated May 26, 1977, requesting that the Food and Drug Administration (FDA) take the following action:

1. Recognition of the FDA's jurisdiction over cigarettes containing nicotine (or nicotine separately) as a "drug" or, in the alternative, as a "device" pursuant to 21 U.S.C. 321.
2. Regulation of cigarettes no less strictly than saccharin.
3. Restriction of the sale of cigarettes containing nicotine to pharmacies pursuant to 21 U.S.C. 353.

At a meeting on July 28, 1977, between you and Dr. Luther Terry, representing the petitioner, and several

employees of FDA and me, the petition was discussed. You stated that the petitioners planned to submit additional material supplementing the petition, and that the supplement would be filed with FDA in September 1977. This supplement was submitted on November 15, 1977.

The petition submitted on May 26, 1977, and the supplemental memorandum of November 15, 1977, have been reviewed. Your requests that FDA assert jurisdiction over cigarettes containing nicotine (or nicotine separately) as a drug under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321 *et seq.*, and that FDA restrict the sale of cigarettes to pharmacies under 21 U.S.C. § 353 are denied. However, FDA can assert jurisdiction over cigarettes containing nicotine (or nicotine separately) as a drug when a jurisdictional basis for doing so exists, e.g., health claims made by the vendors *Fairfax Cigarettes, infra* and *Trim Reducing Cigarettes, infra*.

The request in your petition that FDA regulate the sale of cigarettes no less strictly than saccharin is withdrawn in your supplemental memorandum; therefore, no response to this request is necessary. The request in your petition that FDA assert jurisdiction over cigarettes as a device pursuant to 21 U.S.C. § 321 will be responded to by FDA in connection with your planned separate petition, on FDA regulation of cigarette filters as devices, to which you refer on page five of your supplemental memorandum. The Agency will respond to the separate petition and to your request for FDA regulation of cigarettes as a device within 180 days of the receipt of your separate petition, (21 C.F.R. § 10.30(e)).

The petitioners state in the supplemental memorandum that the serious health hazard posed by the extensive variety of additives in cigarettes and the clear absence of regulatory authority in any other Federal Agency are compelling reasons for the FDA to exercise its jurisdiction and strong evidence that such jurisdiction has not been precluded. Petitioners themselves answer these contentions by admitting at pages 9 and 10 of the supplemental memorandum that no law controls the additives to cigarettes.

Insofar as ASH is aware, there is no law which would prohibit cigarette manufacturers from adding to their products additional additives or tobacco substitutes, whether these contain natural products like lettuce leaves, chemical compounds such as Cytrel or NSM, or even known or suspected carcinogens. Moreover, no law appears to require the manufacturers to report such changes in the compositions of their products either to the consumers or to any federal or state agency.

FDA cannot assert jurisdiction over additives in cigarettes unless FDA has statutory jurisdiction over the cigarettes. FDA has asserted jurisdiction over cigarettes when a jurisdictional basis for so doing has existed (*Fairfax Cigarettes, infra* and *Trim Reducing Cigarettes, infra*).

Two court decisions in the 1950's demonstrate that FDA has regulated cigarettes when health claims were made by the manufacturers. In *United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes*, 113 F. Supp. 336 (D. N.J., 1953), the Court held that the cigarettes were a drug within the meaning of the

Federal Food, Drug, and Cosmetic Act (the Act) because the advertising suggested that the cigarettes were effective in preventing respiratory and other diseases. These drug claims brought the cigarettes within the term "drug" as used in the Act. The other case, *United States v. 354 Bulk Cartons Trim Reducing Cigarettes*, 178 F. Supp. 847 (D. N.J., 1959), involved cigarettes containing tartaric acid, which were represented to be effective for combatting [*sic*] obesity. On the basis of the weight-reducing claims made on the packages and in other advertising, the Court held that these cigarettes constituted a drug.

One decision that has been discussed frequently in connection with the conclusion that cigarettes are not a drug under the Act is *Federal Trade Commission v. Liggett & Myers Tobacco Co.*, 108 F. Supp. 573 (S.D. N.Y., 1952), *affirmed* 203 F.2d 955 (2nd Cir., 1953). The Court construed the definition of the term "drug" in the Federal Trade Commission Act—which is the same definition as in the Federal Food, Drug, and Cosmetic Act—not to include cigarettes. At page 577, the Court stated: "The legislative history, such as it is, coupled with indications of contemporaneous administrative interpretation leads me to the conclusion that Congress, had the matter been considered, would not have intended cigarettes to be included as an article 'intended to affect the functions of the body of man' or in any other definition of 'drug'."

No court has held that cigarettes are a drug under the Act. The interpretation of the Act by FDA consistently has been that cigarettes are not a drug unless health claims are made by the vendors.

Your petition focused the argument that cigarettes are a drug under the Act of the statutory definition of the term "drug" in 21 U.S.C. 321(g)(1)(C):

articles (other than food) intended to affect the structure or any function of the body of man or other animals. . .

The meaning of the word "intended" in 21 U.S.C. § 321 was construed in a 1977 appellate court decision, *National Nutritional Foods Ass'n. v. Mathews*, 557 F.2d 325 (2nd Cir., 1977). The Court stated: "The vendors' intent in selling the product to the public is the key element in this statutory definition" (557 F.2d at 333). The court stated that the Commissioner of Food and Drugs had acted arbitrarily and capriciously in proposing to regulate high potency Vitamin A and D preparations [sic] as drugs under the Act.

The determination that an article is properly regulated as a drug, however, is not left to the Commissioner's unbridled discretion to act to protect the public health but must be in accordance with the statutory definition. Toxicity is not included as an element in the statutory definition of a drug. It is relevant as a factor supporting the Commissioner's classification under § 201(g)(1)(B), but only to the extent that it constitutes objective evidence of therapeutic intent. 557 F.2d at 334-335.

The petitioners have presented no evidence that manufacturers or vendors of cigarettes represent that the cigarettes are "intended to affect the structure or any function of the body of man. . ." 21 U.S.C. § 321(g)(1)(C). Statements by the petitioners and citations in the petition that cigarettes are used by smokers to affect the structure or any functions of their bodies

are not evidence of such intent by the manufacturers or vendors of cigarettes, as required under the provisions of 21 U.S.C. § 321(g)(1)(C) (see *National Nutritional Foods Ass'n.*, *supra*, at 355).

The petitioners cite *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784 (1968), for a liberal construction of the Act consistent with its overriding purpose to protect the public health. In evaluating this contention, the court in *National Nutritional Foods Ass'n.*, *supra* at 336, stated:

The drug definition is to be given a liberal interpretation in light of the remedial purposes of the legislation, *see, United States v. An Article of Drug . . . Bacto-Unidisk* (citation omitted), but when an FDA determination that an article is a "drug" is so directly in conflict with the statutory definition, it must be invalidated as arbitrary and capricious and not in accordance with law.

Therefore, your request that FDA regulate cigarettes as a drug under the Act is denied. Based upon this conclusion, your requests that FDA restrict the sale of cigarettes to pharmacies pursuant to the Act and that FDA assert its jurisdiction over additives in cigarettes are also denied. Upon receipt of a separate petition requesting FDA regulation of cigarette filters as devices, the Agency will respond to that additional request.

Sincerely yours,

/s/ DONALD KENNEDY

DONALD KENNEDY

Commissioner of Food and Drugs

[SEAL OMITTED]

Department of Health Education and Welfare
Public Health Service
Food and Drug Administration
Rockville, Maryland 20857

November 25, 1980

John F. Banzhaf, III
Peter N. Georgiades
Action on Smoking and Health
2000 H St., NW
Washington, DC 20006

Re: Docket Nos. 77P-0185
78P-0338/CP

Dear Messrs. Banzhaf and Georgiades:

This replies to the pending requests in the petitions filed by Action on Smoking and Health (ASH), et al., on May 26, 1977 (Petition No. 1) and on October 2, 1978 (Petition No. 2), and supplements to them. Your petitions request the Food and Drug Administration (FDA) to recognize its jurisdiction over the following as medical devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h):

(1) Cigarettes containing nicotine (Petition No. 1);

(2) Cigarette filters, which you describe as basically "the 'detached' filter, which is purchased separately from the cigarettes and is installed by the smoker on the end of the cigarette" and "the 'attached' filter [which] . . . is an integral part of many brands of cigarette" (Petition No. 2, pp. 5-6).

ASH also requests that FDA commence rulemaking to determine an appropriate scheme for regulating cigarettes and cigarette filters as medical devices.

We will respond first to Petition No. 1 concerning cigarettes containing nicotine and next to Petition No. 2 concerning cigarette filters. Because we agree with your statement (Petition No. 2, p. 6) that "it is conceptually easier to discuss detached and attached filters separately," we will respond separately with respect to "attached" and "detached" filters. Finally, we will respond to your request that FDA commence rulemaking to determine an appropriate regulatory scheme. In preparing our response, we have considered the comments and other documents filed with the respective petitions in the Dockets Management Branch (formerly the Hearing Clerk's office) as well as the petitions themselves.

I. Cigarettes Containing Nicotine

For the reasons discussed below, we are denying the pending requests in Petition No. 1 concerning cigarettes containing nicotine as "devices."

Petition No. 1 (p. 31) sets forth your view that "cigarettes containing nicotine could be regulated either as 'drugs' or as 'devices.'" As you know, on December 5, 1977, we denied your request to recognize jurisdiction over cigarettes containing nicotine under the definition of "drug" in section 201(g) of the Act, 21 U.S.C. 321(g). That denial has been extensively briefed, both before the District Court and the United States Court of Appeals for the District of Columbia, where the matter is presently pending. (*ASH v. Harris*, D.C. Cir., No. 79-1397). The "drug" issue will not be further discussed here.

Petition No. 1 broadly requests (e.g., p. 31) that FDA recognize jurisdiction over cigarettes as a "device" under section 201(h) of the Act, but does not specifically assert or present evidence that cigarettes are a "device" under the provisions of clauses (1) or (2) of section 201(h), 21 U.S.C. 321(h)(1) or (2). We find that cigarettes are not recognized in the official National Formulary or the United States Pharmacopeia, or any supplement to them, and that there is no evidence in the petition that cigarettes are intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals. Accordingly, insofar as Petition No. 1 may be deemed to request that FDA regulate cigarettes containing nicotine as a "device" under section 201(h)(1) or (2) of the Act, we deny your request.

With respect to the application of section 201(h)(3) of the Act, 21 U.S.C. 321(h)(3), Petition No. 1 asserts that when the definition of "device" was enacted in 1938 it was intended to expand the agency's jurisdiction beyond that provided over "drugs" (p. 30) and that the

"device" category is a far broader category than that of "drug" (p. 31).

The legislative history of the development of the definitions of "drug" and "device" as enacted in 1938 is discussed at length by the Supreme Court in *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 794-800 (1969), where the Court treats the interpretation of the "intended use" portion of both definitions as presenting the same issues when considered under either section 201(g) or then 201(h). The language of current section 201(h)(3) was contained in the "device" definition prior to the "Medical Device Amendments of 1976," (the amendments), Pub. L. 94-295. Petition No. 1 fails to establish that there are any differences between the scope of "device" jurisdiction before and after the amendments that are pertinent to determining whether cigarettes containing nicotine are "intended to affect the structure or any function of the body of man" within the meaning of section 201(h)(3) of the Act. Also, there is no suggestion in the legislative history of the amendments that Congress intended that portion of the definition to be interpreted in a different manner than it had been previously or than the identical language found in the "drug" definition in section 201(g)(1)(C) of the Act, 21 U.S.C. 321(g)(1)(C).

The report on the amendments by the House Committee on Interstate and Foreign Commerce (H.R. Rep. No. 94-853, 94th Cong., 2d Sess., p. 14 (1976)) notes that the purpose of amending the definition is "to draw a clear distinction between a 'device' and a 'drug';" that the definition generally retains provisions of existing law concerning intended use; that those characteristics are also used in the definition of a "drug" in section

201(g) of the Act; but, adds the chemical action and metabolism modification to "remov[e] the gray area that exists under present definitions."

Specifically, there is no evidence in the legislative history that Congress intended to include cigarettes within the definition of "device" nor does the legislative history contain any discussion of a possibility that cigarettes were "devices" within the prior definition.

The amendments were thoroughly considered, and the legislative history discusses the types of products intended to be regulated and the types of health hazards with respect to which the amendments were intended to provide authority. Cigarettes are not mentioned even though Congress was aware of the considerable public discussion of the health hazards of cigarette smoking. It is, therefore, not reasonable to consider cigarettes as "devices" when there was no discussion in the legislative history of congressional intent to provide jurisdiction over cigarettes or to provide authority suitable to the regulation of cigarettes.

FDA has long believed and has repeatedly advised inquirers that cigarettes as customarily marketed are intended solely for smoking purposes or smoking pleasure and are not within FDA's jurisdiction under the Act. Indeed, this interpretation is involved in the pending appeal in *ASH v. Harris*. FDA's long-standing interpretation that it has no jurisdiction over cigarettes, absent evidence of the requisite intended use which brings cigarettes within the Act, is well known. That "statutory construction has been 'fully brought to the attention of the public and the Congress,' and the latter has not sought to alter that

interpretation although it has amended the statute in other respects, [thus,] presumably the legislative intent has been correctly discerned." *United States v. Rutherford*, 99 S. Ct. 2470, 2476 n.10 (1979).

As stated, Congress has long been aware of the agency's interpretation. See, e.g., Hearings Before the Committee on Interstate and Foreign Commerce, House of Representatives, 89th Cong., 2d Sess., on Bills Regulating the Labeling and Advertising of Cigarettes and Relating to Health Problems Associated with Smoking, pp. 13-19 (1964); Hearings Before the Committee on Interstate and Foreign Commerce, House of Representatives, 89th Cong., 1st Sess., on H.R. 2248, etc., Cigarette Labeling and Advertising-1965 (1965); Hearings Before the Consumer Subcommittee of the Committee on Commerce, United States Senate, 92d Cong., 2d Sess., on S. 1454, Public Health Cigarette Amendments of 1971, 239-252 (1972). Although bills have been introduced to amend the Act to include cigarettes, these attempts have failed. See, e.g., H.R. 11280, 84th Cong., 2d Sess. (1956) (to establish standards of purity, quality and fitness for human consumption); S. 2554, 85th Cong., 1st Sess. (1957) (label warning requirement); H.R. 592, 85th Cong., 1st Sess. (1957); S. 1682, 88th Cong., 1st Sess. (1963); H.R. 5973, 88th Cong., 1st Sess. (1963). H.R. 2248, 89th Cong., 1st Sess. (1965); H.R. 279, 96th Cong., 1st Sess. (1979). Evidence in the legislative history of those bills indicates that the bills were intended to expand, and not merely to clarify, FDA's jurisdiction under the Act. For example, when Senator Moss introduced S. 1682, he explained that "this amendment simply places smoking products under FDA jurisdiction along with foods, drugs, and cosmetics." 109 Cong. Rec. 10322 (1963).

FDA has, however, occasionally had evidence that cigarettes have been represented as effective for the prevention or treatment of respiratory and other diseases or for weight reduction. FDA has regarded cigarettes which were so represented by manufacturers or vendors as "drugs". See, e.g., *United States v. 46 Cartons . . . Fairfax Cigarettes*, 113 F. Supp. 336 (D. N.J. 1953); *United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (D. N.J. 1959).

An article may be within FDA's jurisdiction if there is objective evidence that the manufacturer or vendor intends that the article is to affect the structure or a function of the body. In determining the intended use of a product, FDA considers the expressions of the person legally responsible for its labeling and the circumstances surrounding its distribution. Petition No. 1 does not contain examples of any representations by the manufacturers or vendors of cigarettes establishing that cigarettes are intended to affect the structure or any function of the body of man.

Petition No. 1 (p. 5) asserts that cigarettes per se affect the structure and functions of the body. However, effects alone do not establish jurisdiction under section 201(h)(3) of the Act. Even assuming the accuracy of the assertions as to the effects of cigarettes, the petition does not establish that these effects are intended.

Evidence of consumer intent in using a product can be relevant in determining the intended use of the product, and we have considered the evidence of consumer intent presented in Petition No. 1. ASH asserts

that consumers use cigarettes with the intent of affecting the structure or functions of their bodies but the petition does not establish this contention. Indeed, petitioners admit (e.g., Petition No. 1, p. 2) that consumers smoke for a variety of reasons.

After a review of all the evidence on Petition No. 1, we conclude that the evidence presented by petitioners fails to establish that cigarettes are intended "to affect the structure or any function of the body" within the meaning of section 201(h)(3) of the Act.

In addition, we have considered whether granting your request to assert jurisdiction over cigarettes as "devices" would require action precluded by another act of Congress, specifically the Federal Cigarette Labeling and Advertising Act (FCLAA), 15 U.S.C. 1331-1340, as amended (Petition No. 1, pp. 20-30 and Exhibit IX).

In enacting the FCLAA, Congress was aware that FDA does not consider cigarettes, absent evidence of the requisite intended use, to be within FDA's jurisdiction under the Act. See, e.g., Hearings on H.R. 2248, etc., at 193 (1965). In a March 22, 1965, letter to the Chairman of the Senate Committee on Commerce concerning cigarette labeling and advertising, the Secretary of then Department of Health, Education, and Welfare (HEW) Anthony J. Celebrezze recommended that regulatory authority concerning cigarette labeling be vested in HEW. Secretary Celebrezze argued that HEW should be authorized to require statements on the labeling of cigarette packages and to prohibit or regulate the use of statements that might give consumers the misleading impression that a given

cigarette is safer than others. Hearings Before the Committee on Commerce, United States Senate, 89th Cong., 1st Sess., on S. 559 and S. 547, Bills to Regulate Labeling of Cigarettes and For Other Purposes, pp. 22-26 (1965). Secretary Celebrezze recommended that the preferable manner for vesting regulatory responsibility would be by way of amendment to the federal Hazardous Substances Act (FHSA). Rather than providing the regulatory authority recommended by HEW, Congress mandated a specific warning, and preempted the imposition of a requirement of any other statement relating to smoking and health on cigarette packages. Similarly, Congress opted for the requirement of reports to Congress concerning smoking and cigarette labeling, including recommendations for legislation. We believe that the FCLAA, as amended, and its legislative history is strong evidence that Congress did not intend cigarettes as customarily marketed, and absent evidence of the requisite intended use, to be regulated by FDA under the Act.

We are also mindful of the fact that Congress has specifically excluded tobacco or tobacco products from the coverage of other statutes that otherwise might have applied to them. Thus, tobacco or tobacco products were excluded from the definition of "hazardous substance" under the FHSA, 15 U.S.C. 1261(f)(2); from the definition of "consumer product" under the Consumer Product Safety Act, 15 U.S.C. 2052(a)(1)(B); from the definition of "chemical substance" under the Toxic Substances Control Act, 15 U.S.C. 2602(2)(B)(iii); from the definition of "controlled substance" under the Controlled Substances Act, 21 U.S.C. 802(6); and from the definition of "consumer commodity" under the Fair Packaging and Labeling Act, 15 U.S.C. 1459(a)(1).

Those actions are indicative of the policy of Congress to limit the regulatory authority over cigarettes by Federal agencies. This is particularly true of the amendment of the FHSA to specifically exclude tobacco and tobacco products from the definition of "hazardous substance," 15 U.S.C. 1261(f)(2), enacted in response to *American Public Health Ass'n v. Consumer Product Safety Comm'n*, Civil Action No. 94-1222 (D.D.C. April 23, 1975) (Exhibit IX to Petition No. 1). That case had held that the Consumer Product Safety Commission (CPSC) had jurisdiction to consider the promulgation of a rule banning high tar cigarettes from interstate commerce. S. Rep. No. 94-251, 94th Cong., 2d Sess. 5 (1976). See also the letter from Elmer B. Staats, Comptroller General, to the Hon. Sam J. Ervin, Jr., Chairman, Senate Committee on Government Operations, 120 Cong. Rec. S. 6225, 6227 (daily ed. April 24, 1974), advising that, although the definition of "hazardous substance" might literally include tobacco products, the FCLAA and its amendments "preempt the field of cigarette smoking and its relation to health."

For the above reasons, FDA is denying your request to assert jurisdiction over cigarettes containing nicotine as "devices" under the Act.

II. Attached Cigarette Filters.

Pctition No. 2 requests that FDA recognize jurisdiction over attached cigarette filters, which ASH describes as an "integral part of many brands of cigarette" (p. 6), as "devices" under section 201(h)(2) of the Act. For the reasons discussed below, we are denying this request.

ASH asserts that the manufacturers of cigarettes are making implied claims that bring attached filters within the definition of device. Petition No. 2 provides examples of filter cigarette labeling and advertising, all of which include representations as to the level of tar, nicotine, or other constituents of cigarettes or of cigarette smoke. ASH contends (Petition No. 2, p. 3) that ". . . cigarette filters, which are designed and sold to remove tar, nicotine or harmful gases from tobacco smoke fall squarely within th[e] literal language" of the statutory definition of "device". In addition, ASH asserts that "cigarette manufacturers are using a wide variety of filters and each is making express or implied claims that the use of its filter will mitigate, treat or prevent smoking-related diseases by removing the 'tar,' nicotine or gases from the tobacco smoke" (Petition No. 2, p. 14).

In this connection, we have also reviewed the cigarette advertisements presented to the Anesthesiology Device Section of the Respiratory and Nervous System Devices Panel (formerly the Anesthesiology Device Classification Panel). In addition, we have considered the transcript of the Panel's deliberations concerning cigarette filters and the conclusion of the Panel that attached cigarette filters are "devices." We do not agree with the Panel's assessment of advertisements for filtered cigarettes and find that the advertisements presented to the Panel are of the same nature as the filter cigarette advertisements attached to Petition No. 2.

Representations in cigarette labeling or advertising of the nature of those in the record of Petition No. 2 as to the absolute or relative quantity of hazardous

constituents of cigarette smoke or as to the safety of the cigarettes do not make the cigarettes or their filters intended for use in the mitigation, treatment, or prevention of disease.

The representations in the filtered cigarette labeling and advertising in Petition No. 2 are made in the context of long-standing public discussion of potential health hazards of smoking and, in recent years, of warnings which have been statutorily required on cigarette packages. ASH provided in Petition No. 2 as "good examples" (p. 11) of implied claims a series of advertisements (Exhibits H-O) (see also pp. 11-14 and Exhibits P-W). ASH itself admits that the advertisements do not imply that there is a health benefit for which purpose the filter cigarettes should be used, absent the desire to smoke (p. 12; see also Petition No. 1, p. 34).

Where, as here, attached filters are at most represented as making the cigarettes to which they are attached less hazardous to smoke, neither the cigarettes nor the filters are thereby intended for use in the mitigation, treatment, or prevention of disease.

FDA or its employees may have previously responded in a different manner to inquiries about cigarettes. FDA's position concerning representations of the types discussed above for cigarettes with attached filters is set forth herein and any inconsistent prior statements or opinions issued by or on behalf of FDA or any of its employees are hereby rescinded.

ASH asserts that objective evidence other than manufacturers' claims can be material to a deter-

mination of intended use under the statutory definition, and that *National Nutritional Food Ass'n v. Food and Drug Administration*, 504 F.2d 761 (2d Cir. 1974), *cert. denied*, 420 U.S. 946 (1975), is authority for this interpretation (Petition No. 2, p. 21). We agree. However, the court there held that the vendor's intent is the crucial element in the statutory definition and that objective evidence sufficient to pierce the manufacturer's subjective claims must be presented (504 F.2d at 789).

As Petition No. 2 also discusses, in *National Nutritional Foods Ass'n v. Weinberger*, 512 F.2d 688 (2d Cir. 1975), the court indicated that a finding that the product was used by consumers almost exclusively for therapeutic purposes could support a determination that the product was *intended* for use in the cure, mitigation, prevention, or treatment of disease (512 F.2d at 703). In *National Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325 (2d Cir. 1977), the court reiterated that vendor intent in selling a product to the public is the key element in the statutory definition (557 F.2d at 333). Those cases support FDA's position that it is the intent of the manufacturers or vendors that objective evidence must establish and that evidence of consumer use can be one element of objective evidence to be weighed in determining if the intended purpose of a product subjects it to regulation under the Act. ASH has not established that consumers use attached cigarette filters for the prevention, mitigation, or treatment of disease to the extent necessary to allow FDA to impute the requisite intended uses to manufacturers or vendors.

The evidence presented in Petition No. 2 concerning consumer intent regarding attached filters establishes at most that many consumers may regard attached filters as reducing exposure to hazardous constituents of cigarettes and creating a "safer" cigarette. As noted above, this will not bring attached filters within the definition of "device".

Because attached filters are necessarily used with the cigarettes of which they are constituent parts, the intent of consumers in using attached filters is reasonably understood and assessed together with consumer intent with respect to filtered cigarettes. ASH has not asserted that cigarettes with filters are intended to prevent, mitigate, or treat disease. Petition No. 1 expressly disclaims reliance on such an assertion when it discusses *FTC v. Liggett & Myers Tobacco Co.*, 180 F. Supp. 573 (S.D.N.Y. 1952), *aff'd*, 203 F.2d 955 (2d Cir. 1953). Petition No. 1 characterizes as "tenuous" the very line of reasoning that Petition No. 2 relies upon in asserting that attached cigarette filters are intended to mitigate, treat, or prevent disease (Petition No. 1, p. 17).

We have also considered ASH's arguments concerning the intent of researchers, and find that the material in Petition No. 2 concerning that intent does not lead to different conclusions than does the evidence of consumer intent regarding attached filters.

For these reasons, FDA is denying your request to assert jurisdiction over attached filters as "devices" under the Act. We believe that congressional consideration of cigarettes included filter cigarettes and, as discussed in Section I, supports our conclusion that

attached filters, as customarily marketed, are not within FDA's jurisdiction.

III. Detached Filters

ASH contends that detached filters, which are purchased separately from cigarettes and "installed by the smoker on the end of the cigarette" (Petition No. 2, p. 6), are subject to FDA's jurisdiction because:

1. Detached filters are advertised as useful in the mitigation, treatment, or prevention of disease (p. 6); or
2. Detached filters are advertised as useful aids in efforts to stop smoking and, therefore, are articles intended to affect the structure or function of the body or to mitigate, treat, or prevent disease (p. 8); or
3. Consumers use detached filters intending to mitigate, treat, or prevent disease (p. 16).

For the reasons stated below, the requests in Petition No. 2 with respect to detached filters are granted in part and denied in part.

We have reviewed the labeling and advertising submitted in Petition No. 2 concerning detached filters to determine whether representations for these products establish that detached filters are intended to be used to mitigate, treat, or prevent disease or to affect the structure or function of the body. We agree that some of that labeling and advertising establishes that manufacturers of certain detached filters, i.e., One Step At A Time, Venturi, and Nu Life Smokers Kit, have made

representations that would bring these products under the device definition and, thus, FDA's jurisdiction.

The labeling and advertising submitted for other detached filters, i.e., Aquafilter and Medico Charcoal Filters, do not establish that these products are intended for a purpose that would bring them within the definition of device.

We would point out that all of the detached filters for which labeling and advertising were submitted in Petition No. 2 are intended to reduce the amount of tar, nicotine, or gases inhaled by the smoker or to aid the smoker to reduce or stop smoking. This does not establish manufacturer intent to mitigate, treat, or prevent disease, or to affect the structure or function of the body. As noted in Section II, we do not agree with the assertion in Petition No. 2 that "cigarette filters which are designed and sold to remove tar, nicotine or harmful gases from tobacco smoke" fall squarely within the literal definition of "device." Manufacturers of detached filters which are intended to remove tar, nicotine, and gases or to aid the smoker to reduce or stop smoking may be responding to consumer demand for a low tar, low nicotine, low gas cigarette, or a stop smoking aid to enable them to reduce the costs of smoking or eliminate the odor associated with smoking, etc. Only if detached filters intended for these purposes are coupled with other evidence that, when viewed together, establish the requisite intended use, will the products come within FDA's jurisdiction.

As noted in Section II, a claim of general or comparative safety, without more, will not usually cause a product to be subject to the Act. Many products are

designed and sold to be used to reduce the exposure of humans to hazardous substances. For example, catalytic convertors and lead-free gasoline for use with automobiles are designed to reduce the exposure of humans to lead and hazardous by-products of gasoline combustion. These products, however, are not deemed to be within the Agency's jurisdiction. The determination that a product is properly regulated under the Act is not left to FDA's unbridled discretion but must be in accordance with the statutory definition. *United States v. 62 Cases of Jam*, 340 U.S. 593 (1950).

ASH's contention that consumer use of (or researchers' intent with respect to) detached filters brings these products within FDA's jurisdiction is identical to petitioner's discussion of attached filters. Our position is the same as discussed under Section II of this letter, as supplemented by our discussion above of evidence of intended use.

Therefore, Petition No. 2 has not provided evidence establishing FDA's jurisdiction over all detached filters. As stated above, we have concluded that FDA has jurisdiction over particular detached filters for which the evidence of the requisite intended use has been shown in Petition No. 2. The evidence in Petition No. 2 has also established that detached filters have been marketed with labeling and advertising which do not provide evidence of the requisite intended use.

FDA may have previously responded to inquiries regarding detached cigarette filters intended to aid the smoker to reduce or stop smoking. As noted under Section II with respect to attached filters, this response sets forth FDA's position and rescinds any earlier

correspondence or opinions concerning detached filters that may be in conflict.

IV. Rulemaking

ASH has requested that FDA commence rulemaking proceedings to establish the means by which FDA should exercise its jurisdiction over cigarettes and attached and detached filters as medical devices. In the FEDERAL REGISTER of November 2, 1979, FDA stated that it was not issuing a proposed regulation to classify cigarette filters pending action on ASH's petition (44 FR 63292 at 63299). ASH's request to commence rulemaking is granted in part and denied in part.

Insofar as rulemaking would relate to cigarettes or attached filters as customarily marketed, we have concluded that FDA has no jurisdiction under section 201(h) of the Act. Therefore, no rulemaking is permissible as a matter of law.

Insofar as rulemaking would relate to detached filters, we have concluded that FDA has jurisdiction under section 201(h) of the Act over some, but not all, detached filters. We are granting your request that FDA institute rulemaking with respect to those detached filters over which FDA has jurisdiction.

In accordance with 21 CFR Part 860, FDA will propose to classify detached filters that are medical devices. FDA currently does not intend to institute other rulemaking proceedings specifically for these detached filters. However, rulemaking that FDA institutes with respect to other articles may also be applicable to detached filters that are devices.

Sincerely yours,

/s/ [ILLEGIBLE]
For JERE E. GOYAN
Commissioner of Food and Drugs

JUL 12 1999

No. 98-1152

OFFICE OF THE CLERK

In the Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, ET AL.,
PETITIONERS

v.

BROWN AND WILLIAMSON TOBACCO CORP., ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

BRIEF FOR THE PETITIONERS

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QUESTION PRESENTED

The Federal Food, Drug, and Cosmetic Act authorizes the Food and Drug Administration (FDA) to regulate products as "drugs" or "devices" when they are "intended to affect the structure or any function of the body." 21 U.S.C. 321(g)(1)(C) and (h)(3). FDA has found that the nicotine in tobacco products is intended by tobacco manufacturers to cause and sustain a user's addiction to nicotine and to act as a sedative, stimulant, and appetite suppressant. The question presented is whether, given that finding, tobacco products are subject to regulation under the Act as "drugs" and "devices."

II

PARTIES TO THE PROCEEDING

The petitioners are: Food and Drug Administration, and Jane E. Henney, Commissioner of Food and Drugs.

The respondents are: Brown and Williamson Tobacco Corp.; Lorillard Tobacco Company; Philip Morris, Incorporated; RJ Reynolds Tobacco Company; Coyne Beahm, Incorporated; National Association of Convenience Stores; ACME Retail, Incorporated; United States Tobacco Company; Conwood Company, LP; National Tobacco Company, LP; Pinkerton Tobacco Company; Swisher International, Incorporated; Central Carolina Grocers, Incorporated; J.T. Davenport, Incorporated; North Carolina Tobacco Distributors Committee, Incorporated; The American Advertising Federation; American Association of Advertising Agencies; Association of National Advertisers, Incorporated; Magazine Publishers of America; the Outdoor Advertising Association of America, Incorporated; and Point of Purchase Advertising Institute.

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BROWN AND WILLIAMSON TOBACCO CORP., ET AL.

ON WRIT OF CERTIORARI
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FOR THE FOURTH CIRCUIT

BRIEF FOR THE PETITIONERS

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-75a) is reported at 153 F.3d 155. The opinion of the district court (Pet. App. 76a-136a) is reported at 966 F. Supp. 1374. The Food and Drug Administration's jurisdictional determination and final rule concerning tobacco products are published at 61 Fed. Reg. 44,396 (1996), and 61 Fed. Reg. 44,619 (1996).¹

JURISDICTION

The judgment of the court of appeals was entered on August 14, 1998. A petition for rehearing was denied on November 10, 1998. Pet. App. 137a-146a. The petition for a writ of certiorari was filed on January 19, 1999, and was granted on April 26, 1999. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

¹ Copies of the Federal Register notices containing the final rule and jurisdictional determination have been lodged with the Court.

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The relevant provisions of the Federal Food, Drug, and Cosmetic Act appear in an appendix to this brief. The tobacco product regulations appear in the appendix to the petition for a writ of certiorari.

STATEMENT

1. The Federal Food, Drug, and Cosmetic Act (Act), ch. 675, 52 Stat. 1040, 21 U.S.C. 301 *et seq.*, confers authority on the Secretary of Health and Human Services, through the Food and Drug Administration (FDA), to regulate "drugs" and "devices" for the purpose of protecting the public health. See 21 U.S.C. 393(b)(1), (2)(B) and (C). The Act defines "drug" as, *inter alia*, "articles (other than food) intended to affect the structure or any function of the body of man or other animal." 21 U.S.C. 321(g)(1). The Act similarly defines "device" as, *inter alia*, "an instrument, apparatus, * * * contrivance, * * * or other similar or related article, including any component, part, or accessory, * * * intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body * * * and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. 321(h)(3).

The Act recognizes that certain products may constitute a combination of a drug and a device. 21 U.S.C. 353(g)(1). FDA may regulate drug/device combination products by using its authority to regulate drugs, its authority to regulate devices, or both. 61 Fed. Reg. 44,400-44,403 (1996). One provision relating to devices authorizes FDA, by regulation, to "require that a device be restricted to sale, distribution, or use * * * upon such * * * conditions as [FDA] may prescribe in such regulation, if, because of its potentiality for

harmful effect or the collateral measures necessary to its use, [FDA] determines that there cannot otherwise be reasonable assurance of its safety and effectiveness." 21 U.S.C. 360j(e)(1).

2. In response to petitions requesting that FDA regulate tobacco products, FDA conducted an extensive investigation, issued a proposed rule and "jurisdictional" analysis, and invited public comment. 60 Fed. Reg. 41,314 (1995). In August 1996, FDA determined that tobacco products constitute a combination of a "drug" and a "device" and issued regulations directed to those products. 61 Fed. Reg. at 44,396; *id.* at 44,619.

FDA based its determination that tobacco products are "drugs" and "devices" on two key findings: (a) extensive scientific documentation establishes that the nicotine in tobacco products "affects the structure or any function of the body" because it causes and sustains addiction, and acts as a sedative, stimulant, and appetite suppressant, 61 Fed. Reg. at 44,630, 44,664-44,685; and (b) those effects are "intended" by the manufacturers of tobacco products. *Id.* at 44,630, 44,686-45,204.

a. In finding that the nicotine in tobacco products affects the structure and function of the body, FDA relied on scientific evidence that nicotine directly affects a part of the brain known as the mesolimbic system, which rewards the repeated consumption of certain pleasurable substances. By increasing the activity of dopamine within that system, nicotine causes the compulsive drug-seeking behavior of drug addiction. 61 Fed. Reg. at 44,700, 44,721. In some circumstances, and in some doses, nicotine in tobacco products acts as a sedative, while in other circumstances and doses, it acts as a stimulant. *Id.* at 44,666. Studies also show that nicotine can cause weight loss. *Ibid.* FDA found that those effects on the structure and function of the body are quintessentially drug-like, identical to those FDA has found in numerous

other products that it regulates under the Act, including stimulants, tranquilizers, appetite suppressants, nicotine replacement products, and narcotics used to treat addiction. *Id.* at 44,632, 44,666-44,670.

b. In finding that the effects of tobacco products on the structure and function of the body are "intended," FDA drew on three categories of evidence.

First, FDA found that nicotine's widely recognized addictive properties make it foreseeable to any reasonable manufacturer that a substantial proportion of users of tobacco products will consume them to satisfy their addiction. 61 Fed. Reg. at 44,701-44,739. FDA also found that nicotine's mood-altering effects and its effects on weight are so well established that a reasonable manufacturer would foresee that tobacco products would be used by a substantial proportion of consumers for those purposes as well. *Id.* at 44,634-44,635, 44,698-44,701, 44,739-44,744. Those findings, FDA determined, are sufficient in themselves to meet the statutory standard of "intended" effects, because "[i]t is a widely accepted legal principle that persons can be held to 'intend' the reasonably foreseeable consequences of their actions." *Id.* at 44,691 (citing, *inter alia*, *Agnew v. United States*, 165 U.S. 36, 53 (1897) ("The law presumes that every man intends the legitimate consequence[s] of his own acts.")).

Second, FDA found that consumers do in fact use tobacco products predominantly for pharmacological purposes. 61 Fed. Reg. at 44,635-44,636, 44,807-44,846. As many as 92% of all cigarette smokers and 75% of all young persons who regularly use smokeless tobacco consume those products because they are addicted to the nicotine in them. *Id.* at 44,635-44,636. Indeed, the percentage of smokers addicted to nicotine is higher than the percentage of heroin and cocaine users addicted to those drugs. *Id.* at 44,812-44,813. More than 70% of young daily smokers and 50% of young

daily smokeless tobacco users consume tobacco products to obtain their mood-altering effects. *Id.* at 44,636. As many as one-half of young persons who smoke do so to control their weight. *Ibid.* Although some people also use tobacco products for their taste or because they like the ritual, those purposes are clearly secondary. *Id.* at 44,807, 44,826-44,827. FDA determined that, "[w]here consumers use a product predominantly or nearly exclusively to obtain any of the effects on the structure or function of the body produced by a substance, such evidence would alone be sufficient to establish manufacturer intent." *Id.* at 44,807 (citing *Action on Smoking & Health v. Harris*, 655 F.2d 236, 239-240 (D.C. Cir. 1980)).

Third, FDA relied on statements, research, and actions of the manufacturers themselves, which showed that the manufacturers intend their products to affect the structure and function of the body. 61 Fed. Reg. at 44,847-45,097. That extensive evidence, FDA concluded, satisfies the standard dictionary definitions of "intend," because it shows that manufacturers "have in mind" the pharmacological effects and uses of their tobacco products and "design" them to enhance those effects and uses. *Id.* at 44,851 & n.413 (quoting, *inter alia*, *The American Heritage Dictionary of the English Language* 668 (2d ed. 1991)).

FDA cited recently discovered evidence that the leading tobacco manufacturers have long known that consumers use tobacco products to obtain the pharmacological effects of nicotine. 61 Fed. Reg. at 44,636-44,640, 44,854-44,915. For example, as early as 1969, the vice president for research and development for Philip Morris informed the board of directors that "the ultimate explanation for the perpetuated cigaret habit resides in the pharmacological effect of smoke upon the body of the smoker." *Id.* at 44,855. In the ensuing decades, Philip Morris researchers described a cigarette as "a dispenser for a dose unit of nicotine," *id.* at 44,856,

observed that cigarettes serve as "a narcotic, tranquilizer, or sedative," *id.* at 44,857, characterized nicotine as "a powerful pharmacological agent with multiple sites of action," *ibid.*, and reported that "it is well recognized within the cigarette industry that there is one principal reason why people smoke—to experience the effects of nicotine, a known pharmacologically active constituent in tobacco," *id.* at 44,858.

Similarly, a memorandum from the early 1970s shows that R.J. Reynolds (RJR) scientists regarded nicotine as a "potent" and "habit-forming" drug, considered cigarettes to be "a vehicle for delivery of nicotine," and conceived of the tobacco industry itself as "a specialized, highly ritualized and stylized segment of the pharmaceutical industry." 61 Fed. Reg. at 44,867. The memorandum also stated that "the confirmed user of tobacco products is primarily seeking the physiological 'satisfaction' derived from nicotine," and that "what we are really selling [is] nicotine satisfaction." *Id.* at 44,868. RJR researchers later reiterated that "[w]ithout any question, the desire to smoke is based on the effect of nicotine on the body," that "a confirmed smoker attempts to get a certain desired level of nicotine," and that "[t]he nicotine in the blood acts upon the central nervous system and produces in the average smoker a sensation one could describe as either stimulating or relaxing." *Id.* at 44,871.

In the 1960s, a senior advisor to the board of British American Tobacco Company (BATCO), the parent company of Brown & Williamson, stated that "smoking is a habit of addiction," and that "nicotine is a very remarkable beneficent drug that both helps the body to resist external stress and also can as a result show a pronounced tranquillising effect." 61 Fed. Reg. at 44,882. During the same period, Brown & Williamson's general counsel stated that "nicotine is addictive" and that "[w]e are, then, in the business of selling nicotine, an addictive drug." *Id.* at 44,884. BATCO researchers also stated that "puffing behaviour is the means

of providing nicotine dose in a metered fashion." *Id.* at 44,890.

FDA further found that cigarette manufacturers acted on the basis of their statements and research concerning the pharmacological effects of tobacco products. In particular, FDA found that "[m]anufacturers of commercially marketed cigarettes commonly manipulate nicotine deliveries to provide remarkably precise, pharmacologically active doses of nicotine to consumers." 61 Fed. Reg. at 44,951. Such manipulation is especially evident in low-tar cigarettes, which make up 80% of the cigarette market. *Id.* at 44,951-44,952. As tar levels are reduced, nicotine levels naturally fall. *Id.* at 44,976. To counteract that effect and to provide an active dose of nicotine in low-tar cigarettes, manufacturers use tobacco blends with higher nicotine content, *id.* at 44,954-44,957, ventilation systems that remove more tar than nicotine from smoke, *id.* at 44,963-44,967, and chemical additives that increase the amount of pharmacologically active nicotine in the smoke, *id.* at 44,970-44,971.

FDA likewise found evidence that manufacturers of smokeless tobacco manipulate nicotine deliveries. They market "starter" brands that have a low level of nicotine, so that new users may develop a tolerance for nicotine without experiencing nausea or vomiting. 61 Fed. Reg. at 44,643. They also market regular brands to experienced users that are engineered to deliver the level of nicotine necessary to sustain addiction. *Ibid.* Through marketing and advertising, manufacturers encourage those who have developed a tolerance for starter brands to graduate to regular brands. *Id.* at 45,120.²

² FDA also relied on evidence that tobacco manufacturers advertise that tobacco products will provide "satisfaction." 61 Fed. Reg. at 45,172-45,178. FDA found that, to the users of tobacco products, the "promise of 'satisfaction' implies that the product will fulfill their craving for the

Finally, although FDA concluded that each of the three categories of evidence just discussed independently supports its determination that manufacturers intend the pharmacological effects and uses of their tobacco products, the cumulative effect and convergence of the evidence "convincingly establishes that cigarettes and smokeless tobacco are 'intended' to affect the structure and function of the body within the meaning of the Act." 61 Fed. Reg. at 45,203-45,204.

c. Having concluded that tobacco products fall squarely within the "drug" and "device" definitions, FDA next examined the structure of the Act as a whole, prior agency statements concerning its authority to regulate tobacco products, Congress's failure to pass legislation that would have expressly authorized FDA to regulate tobacco products, and Congress's enactment of certain tobacco-specific statutes. After carefully evaluating each of those considerations, FDA concluded that none of them detracts from the conclusion that tobacco products are "drugs" and "devices" under the Act. See, e.g., 61 Fed. Reg. at 44,412-44,413 (structure of the Act); *id.* at 45,219-45,252 (prior statements); *id.* at 45,255-45,259 (unenacted legislation); *id.* at 44,544-44,548, 45,261-45,265 (tobacco-specific statutes).

d. In sum, FDA concluded that the nicotine in tobacco products is a "drug," 61 Fed. Reg. at 45,207, that tobacco products contain "device components" for the delivery of that drug, and that cigarettes and smokeless tobacco therefore are "combination products" under the Act. *Id.* at 45,208-45,216.

pharmacological effects of nicotine—satisfying their addiction and providing the sought after mood-altering effects of nicotine." *Id.* at 45,175. In effect, "manufacturers use 'satisfaction' as a code-word for the pharmacological effects of nicotine." *Id.* at 45,178.

3. a. FDA next determined that tobacco use is the largest cause of preventable death in the United States. 61 Fed. Reg. at 44,398. Tobacco kills more Americans annually than AIDS, car accidents, alcohol, homicides, illegal drugs, suicides, and fires combined. *Ibid.* FDA also found that tobacco use is a "pediatric disease," *id.* at 44,421, because most people who use tobacco as adults began smoking regularly during childhood. If adolescents can be kept tobacco-free, most will never start using tobacco as adults. *Id.* at 44,399. Efforts to prevent childhood tobacco use, however, have not been successful thus far. Approximately one million children begin to smoke every year. *Id.* at 44,568. One of every three young people who become regular smokers will die prematurely from a tobacco-related disease. *Id.* at 44,399.

b. Because most tobacco-related addiction begins in childhood, FDA issued regulations aimed at reducing the use of tobacco products by young people. It adopted access restrictions that, *inter alia*: (1) prohibit the sale of tobacco products to persons under age 18; (2) require retailers to check the identification of persons under age 27; and (3) prohibit vending machine sales and self-service displays of tobacco products except in adult-only locations. 61 Fed. Reg. at 44,616-44,617. FDA also issued regulations requiring tobacco product labeling to bear the established name of the product (e.g., "cigarettes") and the statement, "Nicotine-Delivery Device for Persons 18 or Older." *Id.* at 44,617.

Based on evidence that "advertising plays a material role in the decision of children * * * to engage in tobacco use," 61 Fed. Reg. at 44,489, and internal company documents showing the industry's concerted efforts "to attract young smokers" and "presmokers" through advertising, *id.* at 44,480, FDA concluded that restrictions on the forms of advertising that are most effective in attracting young smokers are necessary to complement the access restrictions. *Id.* at 44,406-44,407. FDA's advertising and promo-

tion restrictions include: (1) a requirement that advertisements appear in black-and-white, text-only format, except in adult publications and adult-only facilities; (2) a ban on outdoor advertising within 1000 feet of schools and public playgrounds; (3) a prohibition on the sale or distribution of hats, t-shirts, and other similar promotional products that bear a tobacco product brand name or logo; and (4) a prohibition on sponsorship of athletic, cultural, or other events in a tobacco brand name. *Id.* at 44,617-44,618. In adopting its access, labeling, and advertising restrictions, FDA invoked its authority under 21 U.S.C. 360j(e)(1) to place conditions on the sale, distribution, and use of a device if FDA determines that "there cannot otherwise be reasonable assurance of its safety and effectiveness."

4. Respondents (tobacco companies, advertisers, and retailers) brought suit in the United States District Court for the Middle District of North Carolina, challenging the validity of FDA's tobacco product regulations. Respondents moved for summary judgment, arguing that: (1) FDA lacks statutory authority to regulate tobacco products that are marketed without claims of therapeutic value; (2) FDA lacks statutory authority to regulate advertising of tobacco products; and (3) FDA's advertising restrictions violate the First Amendment. For purposes of their summary judgment motion, respondents accepted as true the facts found by FDA concerning the effects of tobacco products on the human body, and the intent of the manufacturers to cause those effects. Pet. App. 77a-78a n.1.

The district court granted in part and denied in part respondents' motion for summary judgment. Pet. App. 76a-134a. The district court first held that FDA had lawfully concluded that tobacco products are subject to regulation as "drugs" and "devices." *Id.* at 80a-126a. The court reasoned that, given FDA's finding that tobacco products are intended to cause and sustain addiction and to act as a stimulant,

sedative, and weight regulator, tobacco products fit squarely within the Act's definitions of "drug" and "device." *Id.* at 81a, 104a-116a. The court concluded that FDA's previous statements concerning its authority to regulate tobacco products, Congress's failure to enact bills that would have expressly authorized FDA to regulate tobacco products, and the tobacco-specific statutes enacted after 1938 do not detract from the reasonableness of FDA's conclusion that tobacco products are drugs and devices under the Act. *Id.* at 84a-101a.

The district court upheld FDA's restrictions on minors' access to tobacco products as a valid exercise of FDA's authority under 21 U.S.C. 360j(e)(1) to impose conditions on the "sale, distribution, or use" of "devices." Pet. App. 133a. It also upheld FDA's labeling requirements. *Id.* at 134a. The court concluded, however, that FDA's advertising and promotion restrictions are not authorized by Section 360j(e). *Id.* at 127a-133a. The district court certified all of its rulings for interlocutory appeal, *id.* at 135a, and the court of appeals accepted that certification, *id.* at 11a.

5. a. In a 2-1 decision, a panel of the Fourth Circuit reversed, Pet. App. 1a-75a, holding that "FDA lacks jurisdiction to regulate tobacco products," and that "all of the FDA's August 28, 1996 regulations * * * are thus invalid," *id.* at 11a-12a. The majority acknowledged that the plain meaning of the drug and device provisions "may appear to support the government's position that tobacco products fit within the Act's definitions of drugs or devices." *Id.* at 19a. The majority determined, however, that FDA could not rely on the definitional provisions, because, in its view, tobacco products do not fit into the Act's overall regulatory scheme. *Id.* at 20a-30a.

The majority concluded that, under 21 U.S.C. 360j(e), FDA has a responsibility to determine that there is a reasonable assurance of safety of a product that it declines to

ban completely from the market. Pet. App. 21a-22a. Because FDA found tobacco products to be dangerous, the majority concluded, FDA's failure to prohibit the sale of such products does not "comply with the terms of the very statutory provision it has chosen as its basis for regulation." *Id.* at 23a. The majority further concluded that, given FDA's finding that tobacco products are not safe, several other provisions of the Act would require FDA to ban the sale of tobacco products, a result the majority found to be in conflict with what it perceived to be Congress's intent. *Id.* at 23a-30a. The majority concluded that "FDA's need to maneuver around the obstacles created by the operative provisions of the Act reflects congressional intent not to include tobacco products within the scope of the FDA's authority." *Id.* at 29a-30a. The majority also concluded that FDA's previous statements concerning the circumstances in which it would regulate tobacco products, Congress's failure to enact bills that would have expressly authorized FDA to regulate tobacco products, and the tobacco-specific statutes enacted since 1938 all corroborate that Congress did not intend the original grant of authority to FDA to include regulation of tobacco products. *Id.* at 31a-52a.

b. Judge Hall dissented. Pet. App. 55a-75a. Observing that the "record contains voluminous evidence of the pharmacological effects of nicotine," *id.* at 57a, and that such effects are "intended" by tobacco manufacturers, *id.* at 57a-59a, he concluded that "[t]obacco products fit comfortably into the [Act's] definitions of 'drug' and 'device,'" *id.* at 55a. Judge Hall rejected the majority's view that FDA's failure to prohibit the sale of tobacco products, despite finding them to be dangerous, demonstrates that tobacco products are not covered by the Act. *Id.* at 60a-61a. He reasoned that "[h]ow the FDA has chosen to regulate tobacco has no bearing on the question of whether the agency has the authority to regulate it at all." *Ibid.* Judge Hall similarly disagreed with

the majority's reliance on FDA's prior decisions and statements regarding its authority to regulate tobacco products. *Id.* at 63a-65a. He pointed out that "an agency can change its view of what action is possible or necessary, particularly when new facts come to light." *Id.* at 64a. Here, he explained, FDA had a strong basis for changing its position because of new evidence that "nicotine is extremely addictive and that a large majority of tobacco users use the product to satisfy that addiction," and, even more important, because of new evidence that "manufacturers design their products to sustain such addiction." *Id.* at 65a. Judge Hall also disagreed with the majority's reliance on unenacted bills, concluding that any inference that could be drawn from that experience was offset by Congress's inaction following FDA's announcement of its proposed rule to regulate tobacco products. *Id.* at 61a n.1. Finally, Judge Hall concluded that the "tobacco-specific" statutes cited by the majority address narrow subjects and fall far short of showing that Congress intended to prevent FDA from exercising regulatory authority over tobacco products. *Id.* at 65a-70a.

SUMMARY OF ARGUMENT

The Food and Drug Administration reasonably concluded that tobacco products are drugs and devices subject to regulation under the Act. Under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), FDA's conclusion is entitled to controlling weight.

A. The Federal Food, Drug, and Cosmetic Act defines "drug" and "device" to include products "intended to affect the structure or any function of the body," 21 U.S.C. 321(g)(1)(C) and (h)(3), and it does not exempt tobacco products from those definitions. Given FDA's finding that the nicotine in tobacco products is intended by manufacturers to sustain addiction and to act as a sedative, stimulant, and

appetite suppressant, tobacco products plainly qualify as drugs and devices under the Act.

B. Tobacco products also have the classic characteristics of drugs and devices subject to regulation under the Act: They are taken within the human body, they deliver a pharmacologically active substance to the bloodstream, and they have potentially dangerous effects. Moreover, the intended pharmacological effects of tobacco products mirror those of numerous other products that FDA regulates, including tranquilizers, stimulants, weight-loss products, nicotine replacement products, and narcotics used to treat addiction.

Respondents' argument that tobacco products cannot be drugs or devices unless they are accompanied by express claims of therapeutic value is without merit. The text of the Act makes "intended" effects, not "market claims," the decisive factor. When, as here, consumers use a product predominantly for its pharmacological effects, manufacturers know that is why consumers use their products, and manufacturers manipulate the content of the product in order to promote those uses, an intent to affect the structure or function of the body is clearly established. FDA has regulated other products intended to affect the structure or function of the body, despite the absence of explicit market claims, and there is no principled basis for treating tobacco products differently.

C. The court of appeals' view that tobacco products cannot be drugs or devices, because if they were, they would have to be banned, is incorrect. The Act authorizes FDA to permit the continued marketing of drugs and devices, subject to regulation, when it finds that the dangers of banning the product outweigh the benefits. FDA reasonably determined that, with respect to adults, the dangers of banning tobacco from the market outweigh the benefits, because a ban would leave many users with untreatable

symptoms of withdrawal, and would predictably lead to the use of more dangerous black market products. If the Court were to overturn FDA's judgment concerning the risks and benefits of leaving tobacco products on the market, however, that would simply mean that the Act, as presently written, requires tobacco products to be banned. That consequence would in no way undermine FDA's conclusion that tobacco products are intended to affect the structure or function of the body and are therefore drugs and devices subject to regulation under the Act.

D. Until FDA issued the regulations at issue here, the only instances in which it had found that tobacco products were intended to affect the structure or function of the body involved cases in which there were express market claims of therapeutic value. An agency is always free to change its position on an issue, however, as long as it provides a reasoned explanation justifying the change, and FDA provided such a reasoned explanation here. FDA's conclusion that tobacco products are intended to affect the structure or function of the body, regardless of whether manufacturers make express claims of therapeutic value, is based on overwhelming new evidence that nicotine is addictive, that consumers use tobacco products primarily to satisfy addiction and for its mood-altering effects, that manufacturers know that consumers use their products primarily for those purposes, and that manufacturers have engineered their products to deliver pharmacologically active doses of nicotine.

Nor is it significant that Congress has failed to enact bills that would have expressly authorized FDA to regulate tobacco products. The Constitution requires Congress to express its will through enacted legislation, not unenacted bills. Congress's failure to enact bills that would have expressly authorized FDA to regulate tobacco products therefore has no more bearing on the question presented in this case than does Congress's failure to enact other bills

that would have excluded tobacco products from the reach of the Act.

Finally, the tobacco-specific statutes enacted long after 1938 do not affect the question presented here. Those statutes address narrow issues, such as what warning labels should be placed on cigarette packages. None of those statutes exempts tobacco products from the reach of the Federal Food, Drug, and Cosmetic Act, and none of them remotely implies that FDA altogether lacks authority to regulate tobacco products.

ARGUMENT

THE FOOD AND DRUG ADMINISTRATION VALIDLY DETERMINED THAT TOBACCO PRODUCTS ARE "DRUGS" AND "DEVICES" WITHIN THE MEANING OF THE ACT

After the most extensive rulemaking hearing in its history, the Food and Drug Administration determined that the nicotine in tobacco products is intended by tobacco manufacturers to cause and sustain addiction and to act as a stimulant, sedative, and appetite suppressant. The sole question presented in this case is whether, given that finding, FDA validly determined that tobacco products are subject to regulation as "drugs" and "devices" under the Act.

Because Congress has conferred on FDA the authority to administer the Act, 21 U.S.C. 393(d)(2) (1994 & Supp. III 1997), and to issue regulations to carry out its purposes, 21 U.S.C. 371(a), FDA's conclusion that tobacco products are drugs and devices is subject to review under the standard set forth in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Under *Chevron*, unless Congress has "unambiguously expressed [its] intent" and "directly addressed the precise question at issue," the question for a court is whether the agency's view is based on

a "permissible construction" of the Act. *Id.* at 843. That means that "a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency." *Id.* at 844. Rather, when the agency "fills a gap or defines a term in a way that is reasonable in light of the legislature's revealed design," a court must give the agency's view "controlling weight." *Ibid.* As we now demonstrate, FDA reasonably concluded that tobacco products are subject to regulation under the Act as "drugs" and "devices." The Court should therefore give FDA's interpretation controlling weight.³

A. FDA's Interpretation Is Supported By The Plain Language, Structure, And Drafting History Of The Drug And Device Definitions

1. Rather than identifying specific products that FDA may regulate as "drugs" and "devices," Congress enacted

³ The court of appeals appeared to question the applicability of *Chevron* for two reasons. First, the court noted (Pet. App. 16a) that, under *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649 (1990), "[a] precondition to deference under *Chevron* is a congressional delegation of administrative authority," suggesting that the court believed that such a delegation is absent here. *Adams Fruit* holds that an agency is not entitled to deference when it does not have authority to enforce the statutory provision at issue. *Ibid.* Because Congress has conferred authority on FDA to regulate drugs and devices, *Adams Fruit* is inapplicable here. Second, the Fourth Circuit suggested (Pet. App. 16a) that an agency is entitled to diminished deference when it attempts "to expand the scope of its jurisdiction." As long as an agency is reasonably interpreting a statutory provision it enforces, however, *Chevron* deference applies. It is not relevant whether the agency's proposed interpretation can be said to affect its jurisdiction. *Chevron*, 467 U.S. at 844 (an agency is entitled to deference on the "reach of a statute" it is authorized to enforce). See *Commodity Futures Trading Comm'n v. Schor*, 478 U.S. 833, 844-845 (1986); *NLRB v. City Disposal Sys., Inc.*, 465 U.S. 822, 830 n.7 (1984); see also *Mississippi Power & Light Co. v. Mississippi ex rel. Moore*, 487 U.S. 354, 380-382 (1988) (Scalia, J., concurring) (collecting cases).

comprehensive definitions of those terms. Products that fall within those definitions, unless expressly exempted, are subject to the Act's regulatory regime. The Act defines "drug" as:

(A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (*other than food*) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph.

21 U.S.C. 321(g)(1) (emphasis added). The Act similarly defines "device" as, *inter alia*, "an instrument, apparatus, * * * contrivance, * * * or other similar or related article, including any component, part, or accessory, * * * intended to affect the structure or any function of the body of man or other animal, and which does not achieve its primary intended purposes through chemical action within or on the body and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. 321(h)(3).

Significantly, the Act does not exempt tobacco from the drug and device definitions. In contrast, the Act does specifically exclude "food" from the very "structure-function" definition of "drug" at issue here, 21 U.S.C. 321(g)(1)(C), and exempts "tobacco" itself from the definition of "dietary supplement," 21 U.S.C. 321(ff)(1). See also 21 U.S.C. 321(i) (exempting "soap" from the definition of "cosmetic"; 21 U.S.C. 321(s) (1994 & Supp. III 1997) (exempting "pesticides" in certain circumstances from the definition of

"food additive"). Congress has also specifically exempted tobacco products from many other laws, including the Federal Hazardous Substances Act, 15 U.S.C. 1261(f)(2), the Fair Packaging and Labeling Act, 15 U.S.C. 1459(a)(1), the Consumer Products Safety Act, 15 U.S.C. 2052(a)(1)(B), the Toxic Substances Control Act, 15 U.S.C. 2602(2)(B)(iii), and the Controlled Substances Act, 21 U.S.C. 802(6). Accordingly, the overwhelming implication from the text and structure of the "drug" and "device" definitions is that tobacco products, like all other products not specifically exempted, are subject to regulation as "drugs" and "devices" if they are "intended to affect the structure or any function of the body." 21 U.S.C. 321(g)(1)(C) and (h)(3).

2. Given the extensive evidence before FDA, and FDA's findings based on that evidence, tobacco products plainly qualify as "drugs" and "devices" under that statutory standard. The evidence established that: (1) nicotine in tobacco products causes and sustains addiction and acts as a sedative, stimulant, and appetite suppressant; (2) most persons who use tobacco products do so in order to obtain those effects; (3) tobacco manufacturers know that most consumers use their products for those purposes; (4) tobacco manufacturers themselves characterize nicotine as a powerful drug and cigarettes as a vehicle for delivering nicotine; (5) the manufacturers design their products to deliver pharmacologically active doses of nicotine; and (6) the manufacturers market their products with claims that they will provide "satisfaction," a "code-word" for the pharmacological effects of nicotine. See pp. 3-8, *supra*. Based on that compelling evidence, FDA found that the nicotine in tobacco products is intended by manufacturers to cause and sustain addiction, and to act as a sedative, stimulant, and appetite suppressant. In light of that critical finding, tobacco products fit squarely within the "drug" and "device" definitions—they are, without question, "intended to affect the structure or any func-

tion of the body." 21 U.S.C. 321(g)(1)(C) and (h)(3). Thus, the plain language of the Act, which is the starting point in resolving any question of statutory construction, *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 241 (1989), provides powerful support for FDA's conclusion that tobacco products are "drugs" and "devices" under the Act.

3. The history of the Act provides additional support for FDA's conclusion. Before the Act was passed in 1938, the Pure Food and Drugs Act defined "drug" to include "articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them," and "any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals." Pure Food and Drugs Act of 1906, ch. 3915, § 6, 34 Stat. 769. In the 1938 Act, Congress expanded the definition of "drug" to include "articles (other than food) intended to affect the structure or any function of the body of man or other animals." § 201, 52 Stat. 1041. The new Act also added a parallel definition of "device." *Ibid.* Congress enacted the new definitions because existing law "contain[ed] serious loopholes" and was "not sufficiently broad in its scope to meet the requirements of consumer protection under modern conditions." H.R. Rep. No. 2139, 75th Cong., 3d Sess. 1 (1938). Congress was particularly concerned about dangerous and ineffective weight-loss products that had escaped regulation under the old drug definition. S. Rep. No. 361, 74th Cong., 1st Sess. Pt. 1, at 239 (1935). Congress understood, however, that the Act would reach well beyond weight-loss products and cover other products intended to affect the structure or function of the body. See H.R. Rep. No. 2139, *supra*, at 2 ("Drugs intended for diagnosing illness or for remedying underweight or overweight or for otherwise affecting bodily structure or function are subjected to regulation.").

The drafting history of the drug and device definitions provides compelling evidence that the definitions were intended to have a scope that is as broad as their language prescribes. Early versions of the bill had included "devices intended to affect the structure or function of the body" within the definition of "drug." S. Rep. No. 493, 73d Cong. 2d Sess. 2 (1934). In hearings on one of those bills, a Member of Congress asked the FDA Administrator whether the drug definition would include "ultraviolet lights and various instruments of that sort." Charles W. Dunn, *Federal Food, Drug, and Cosmetic Act*, App. B at 1053 (1938). The Administrator responded that it would, because the portion of the "drug" definition that encompassed "devices" was "admittedly an inclusive, * * * wide definition." *Ibid.* The Administrator added that the definition would also encompass belts used for therapeutic purposes, explaining that "[t]his definition of 'drugs' is all-inclusive." *Id.* App. C at 1126-1127. Members of Congress later expressed concern that the device portion of the drug definition was so broad as to reach shoulder braces, radium belts, electrical devices, bathroom weight scales, hospital air conditioners, and crutches. *United States v. Bacto-Unidisk*, 394 U.S. 784, 795-796 (1969) (citing relevant debates). The members did not object to the regulation of such products under the Act; instead, they objected to the characterization of such products as drugs. *Id.* at 796-797. In response to that narrow concern, the bill was amended to remove devices from the drug definition and to create a separate definition of "device" that paralleled the new definition of drug. *Ibid.* That solution eliminated the awkwardness of referring to electric belts and therapeutic lamps as drugs, while preserving the bill's broad scope. *Ibid.*

The statutory background and drafting history of the Act show that Congress understood that the definitions of "drug" and "device" would determine what products would

be subject to regulation under the Act, and that the scope of those definitions was intended to be coextensive with their plain language, reaching many products that had not been subject to regulation before. Accordingly, they firmly support FDA's reliance on the plain language of the "drug" and "device" definitions in concluding that, given their intended pharmacological effects, tobacco products are subject to regulation under the Act.⁴

4. This Court's decision in *Bacto-Unidisk* also provides significant support for FDA's analysis. The question in that case was whether an antibiotic sensitivity disc used to determine which antibiotic should be used in treatment of a particular patient was a "drug" under the Act. 394 U.S. at 784. The disc satisfied the literal definition of "drug," because it was intended for use in the cure, mitigation, or treatment of disease. *Id.* at 792. The lower courts had held, however, that the drug definition should be construed to

⁴ As the court of appeals noted (Pet. App. 32a), there is no discussion in the legislative history of the 1938 Act concerning whether tobacco products would or would not be covered as drugs or devices. But that is hardly surprising. At the time, there was not public evidence that the nicotine in tobacco products was intended by manufacturers to cause and sustain addiction and to act as a sedative, stimulant, and appetite suppressant. Moreover, as the discussion in the text demonstrates, Congress deliberately drafted comprehensive definitions of drug and device, and it is that intent, rather than Congress's understanding of the specific products that would be encompassed by those definitions, that is controlling. See *Oncale v. Sundowner Offshore Servs., Inc.*, 523 U.S. 75, 79 (1998) (Since "it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed," it is irrelevant whether the members of Congress who enacted Title VII would have regarded male-on-male sexual harassment as a form of discrimination prohibited by Title VII.); *H.J. Inc. v. Northwestern Bell Tel. Co.*, 492 U.S. 229, 248 (1989) (While "[t]he occasion for" the enactment of the RICO statute was "the perceived need to combat organized crime," Congress "chose to enact a more general statute."). See also note 7, *infra*.

reach only those products that satisfy the medical definition of a drug. *Ibid.* This Court squarely rejected that interpretation and held that the disc was a "drug" within the meaning of the Act. Relying on the text of the Act and the drafting history discussed above, the Court concluded that "the word 'drug' is a term of art for purposes of the Act, encompassing far more than the strict medical definition of that word." *Id.* at 793. The Court further explained that "[t]he historical expansion of the definition of drug, and the creation of a parallel concept of devices, clearly show * * * that Congress fully intended that the Act's coverage be as broad as its literal language indicates—and equally clearly broader than any strict medical definition might otherwise allow." *Id.* at 798. *Bacto-Unidisk* therefore fully supports FDA's reliance on the plain language of the drug and device definitions for its conclusion that, in light of their intended pharmacological effects, tobacco products are drugs and devices under the Act.

B. FDA's Interpretation Is Also Supported By FDA's Prior Regulatory Practice And The Public Health Purposes Of The Act

1. FDA's conclusion that tobacco products are subject to regulation as drugs and devices is also supported by FDA's prior regulatory practice and the public health purposes of the Act. As FDA has explained, the intended pharmacological effects of tobacco products mirror those of numerous other products that FDA regulates, including tranquilizers, stimulants, weight-loss products, and narcotics used to treat addiction. See 61 Fed. Reg. at 44,632, 44,667-44,678. FDA also regulates the sale of other products containing nicotine, such as nicotine patches, nicotine chewing gum, and nicotine nasal spray, and the pharmacological effects of nicotine in tobacco products are far more powerful than those in the other nicotine-containing products. *Id.* at 44,665.

Significantly, moreover, tobacco products have the classic characteristics of drugs and devices subject to regulation under the Act: Tobacco products are taken within the human body, they deliver a pharmacologically active substance to the bloodstream, and they have potentially dangerous effects. 61 Fed. Reg. at 44,628. The resemblance of tobacco products to other products regulated as drugs and devices by the FDA has not escaped the attention of tobacco manufacturers. In their own research, market planning, and deliberations, the manufacturers have referred to the nicotine in tobacco as a drug, to cigarettes as a vehicle for the delivery of nicotine, and to the tobacco industry as a segment of the pharmaceutical industry. See pp. 5-7, *supra*. Because of the similarity between tobacco products and other products regulated by FDA, it is not surprising that FDA has previously regulated tobacco products when it has found sufficient evidence that they were intended to affect the structure or any function of the body, see *United States v. 354 Bulk Cartons* * * * *Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847, 851 (D.N.J. 1959), or that they were intended to treat or prevent disease, see *United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes*, 113 F. Supp. 336, 338-339 (D.N.J. 1953).

2. Respondents have sought to distinguish the products regulated by FDA that have pharmacological effects similar to those of tobacco products on the ground that those products are sold with express therapeutic claims. That distinction, in respondents' view, also explains why it was appropriate for FDA to regulate tobacco products in the two cigarette cases cited above. Under respondents' theory, tobacco products would be subject to FDA regulation only if tobacco manufacturers suddenly decided on a policy of full public disclosure and made express representations that their products cause and satisfy addiction and are intended to be used as a sedative, stimulant, and appetite suppres-

sant. But as long as they refrain from making such claims, respondents argue, tobacco products are not subject to the Act. That remains true, under respondents' theory, even when, as here, there is overwhelming evidence that consumers use tobacco products as sedatives, stimulants, and appetite suppressants and to maintain addiction; that those characteristics of tobacco products are so well known as to render them unquestionably foreseeable to the manufacturers of the products; and that the manufacturers of the products in fact act keenly aware of those effects and uses and manipulate the nicotine content of their products to promote them.

In these circumstances, the pervasive knowledge and conduct on the part of both manufacturers and consumers serve the same function as labeling or other express representations by the manufacturers in identifying the intended effects and uses of the product, thereby rendering any such representations unnecessary. It would be ironic indeed, and contrary to the fundamental public health purposes of the Act, to conclude that a product is altogether excluded from regulation under the comprehensive terms of the Act precisely *because* its basic drug-like qualities are so well documented, widely known, and thoroughly embedded in the behavior of consumers and manufacturers as to render express claims to that effect superfluous. And, not surprisingly, respondents' view that FDA must blind itself to compelling evidence that a product is intended to affect the structure or function of the body simply because a manufacturer has not made any express claims of therapeutic value is at odds with the text of the Act, longstanding FDA regulations, the legislative history of the Medical Device Amendments of 1976, lower court decisions, and FDA's regulatory practice.

The text of the Act makes "intended" effects, not "market claims," the decisive factor. 21 U.S.C. 321(g)(1)(C) and (h)(3).

While market claims are one important way in which a product's intended effects may be established, they are not the only way. As the present case so clearly shows, other circumstances can establish that a product is intended to affect the structure or function of the body. Nothing in the text of the operative definitions bars FDA from relying on such evidence. Moreover, if Congress had wished to establish the statutory standard respondents propose, it could have used terms such as "promoted to," "labeled to," "advertised to," or "represented to" instead of "intended to." Congress used such terms in other provisions of the Act. 21 U.S.C. 321(n) (misbranding may result from "representations" made in "labeling or advertising"); 21 U.S.C. 352(a) (a drug is misbranded if its "labeling" is false or misleading); 21 U.S.C. 352(c) (a drug is misbranded unless its "advertisements and other descriptive printed matter" contain certain true statements). Congress's failure to use those terms in the drug and device definitions is therefore significant: It shows that Congress understood the difference between intended effects and claimed effects, and that it deliberately chose the more comprehensive "intended to affect" formulation to define the products subject to coverage under the Act. See 61 Fed. Reg. at 45,154-45,155.

Consistent with that understanding, FDA regulations that have been in effect for more than four decades provide that "intended use" (or words to that effect) refer to "the objective intent of the persons legally responsible for labeling," and may be determined not only by "labeling claims" and "advertising matter," but also by (1) other "oral or written statements" made by persons legally responsible for the labeling; (2) "the circumstances surrounding the distribution of the article"; (3) "the circumstances that the article is, with the knowledge of [the responsible persons], * * * offered and used for a purpose for which it is neither labeled nor advertised"; and (4) evidence that "a manufac-

turer knows, or has knowledge of facts that would give him notice" that a drug or device "is to be used" for purposes other than those for which the manufacturer offered the products. 21 C.F.R. 201.128 (drug); 21 C.F.R. 801.4 (device).⁵ FDA has further explained that its "objective intent" standard means that FDA will consider all relevant evidence of intent from the perspective of a reasonable fact-finder, and that it is not bound by the intent a manufacturer claims to have. 61 Fed. Reg. at 45,153, 45,184 n.1133. Compare *Posters 'N' Things v. United States*, 511 U.S. 513, 519-522 (1994) (holding that the phrase "primarily intended for use [with illegal drugs]," which is the definition of "drug paraphernalia" in 21 U.S.C. 857(d), "is to be understood objectively and refers generally to the item's likely use").

The legislative history of the Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539, in which Congress revised and reenacted the definition of "device" in its current form, see § 3(a)(i)(A), 90 Stat. 575, confirms the soundness of FDA's interpretation of that definition (and the parallel definition of "drug") as not limiting the "intended" effects of a product to those the manufacturer expressly claims. The House Report stated that, although the major new authorities to be conferred on FDA should be limited to devices intended for human use,

⁵ The regulatory definitions quoted in the text, which were first promulgated in 1952 (see 17 Fed. Reg. 6818 (1952)), define "intended use" for purposes of FDA's labeling regulations. The product labeling regulations require adequate labeling for all "intended uses" of a drug or device. See 21 C.F.R. 201.5 (drugs), 801.5 (devices). As FDA explained in its jurisdictional determination concerning tobacco products (61 Fed. Reg. at 44,693 n.23, 45,157), however, it regularly uses the definitions in the product-labeling regulations not only to identify the intended uses of products that are already classified as drugs or devices, but also to determine whether products should be classified as drugs or devices in the first place.

[t]his is not to say * * * that a manufacturer of a device that is banned by the Secretary [for human use] can escape the ban by labeling the device for veterinary use. The Secretary may consider the ultimate destination of a product in determining whether or not it is for human use, *just as he may consider actual use of a product in determining whether or not it is a device.*

H.R. Rep. No. 853, 94th Cong., 2d Sess. 14 (1976) (emphasis added).

Lower courts likewise have agreed that a manufacturer's intent with respect to effects or use may be determined on the basis of all relevant circumstances, including consumer use, not simply a manufacturer's market claims. *National Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325, 334 (2d Cir. 1977) (intent may be determined from any relevant source, including consumer use); *United States v. An Article * * * Consisting of * * * 216 Cartoned Bottles*, 409 F.2d 734, 739, 742 (2d Cir. 1969) (the intended use of a product may be determined from its label, accompanying labeling, promotional material, advertising and any other relevant source, including consumer use); *United States v. Storage Spaces Designated Nos. "8" & "49"*, 777 F.2d 1363, 1366 (9th Cir. 1985), (manufacturer intent may be derived from any relevant source), cert. denied, 479 U.S. 1086 (1987); *Action on Smoking & Health v. Harris*, 655 F.2d 236, 239-240 (D.C. Cir. 1980) (ASH) (consumer use can be relevant in determining manufacturer intent); see also *United States v. 789 Cases * * * of Latex Surgeons' Gloves*, 799 F. Supp. 1275, 1285, 1294-1295 (D.P.R. 1992); *United States v. An Article of Device * * * "Cameron Spitler Amblyo-Syntonizer"*, 261 F. Supp. 243, 245 (D. Neb. 1966). From a public health perspective, no other result could be justified. The risks to the public health and the appropriateness of regulation under the Act exist regardless of whether intended effects

are established through market claims or by other evidence. See *Bacto-Unidisk*, 394 U.S. at 798 (the Act is to be given a construction "consistent with the Act's overriding purpose to protect the public health").

Finally, in its administration of the Act, FDA has treated products intended to affect the structure or function of the body as drugs or devices, despite the absence of express market claims of therapeutic value. For example, FDA took enforcement action against "caine," a product that contained anesthetic powders and that was often marketed as incense. FDA found that "caine" was intended to be used as a drug, based on a laboratory analysis of its ingredients, its sale in "head shops," and "street" information that it provided a "cheap high." 61 Fed. Reg. at 45,167. Similarly, FDA took enforcement action against "khat," a shrub whose leaves act as a stimulant when chewed or used as tea, even though its vendors did not make any market claims. FDA determined that "khat" was intended for use as a drug based on its actual effects and widely known uses. *Ibid.*

FDA has also treated other products as drugs or devices, despite the absence of explicit market claims. Among other products, FDA has treated as drugs or devices: (1) cosmetics containing hormones based on the absence of any legitimate cosmetic purpose for the hormones; (2) toothpaste containing fluoride because fluoride is widely accepted as an anti-cavity agent and affects the structure of the tooth; (3) thyroid-containing food supplements based on the recognized physiological effects of thyroid products; (4) interferon based on media coverage touting it as a possible miracle cure; (5) novelty condoms based on their likely use as prophylactics; (6) non-corrective tinted contact lenses based on their effects on the eye; (7) sunscreen products based on consumer expectations that they will provide protection against the sun; and (8) tanning booths based on the known effects of ultraviolet rays. 60 Fed. Reg. at 41,528-41,531. In each of the above

cases, FDA found that the product was intended for use as a drug or a device based on the inherent nature of the product, its predominant use or effects, or both. *Id.* at 41,527. There is no principled basis for treating tobacco products differently, especially in light of the compelling evidence that tobacco manufacturers have known for decades that nicotine is addictive and has mood-altering effects and that those are the main reasons that people use tobacco products. Tobacco products should not escape regulation for the protection of the public health simply because tobacco manufacturers refrain from making express claims about the pharmacological effects and uses they so clearly intend and from which they so clearly profit.

C. FDA's Interpretation Is Consistent With The Structure Of The Act As A Whole

The court of appeals rejected FDA's conclusion that tobacco products are drugs and devices in large part because it believed that regulation of tobacco products is inconsistent with the structure of the Act as a whole. The court essentially reasoned as follows: (1) If tobacco products are drugs or devices within the meaning of the Act, the regulatory provisions of the Act would require them to be banned; (2) Congress did not intend for tobacco products to be banned; therefore (3) tobacco products are not drugs and devices. See generally *Pet. App.* 18a-30a. That analysis is seriously flawed. FDA reasonably concluded that the operative regulatory provisions of the Act do not require a ban of tobacco products. Even if the operative provisions of the Act were to require a ban, however, that would not detract from the reasonableness of FDA's conclusion that tobacco products are drugs and devices.

1. In concluding that tobacco products would have to be banned if they are drugs and devices, the court of appeals cited provisions of the Act that either directly prohibit the

marketing of drugs and devices that FDA has found not to be sufficiently "safe," or contemplate that FDA will prevent or otherwise regulate the marketing of such products.⁶ Because FDA determined that tobacco products are dangerous, the court reasoned, those provisions would require tobacco products to be banned if they were "drugs" and "devices." See generally *Pet. App.* 18a-30a.

In deciding whether a drug or device is sufficiently "safe" within the meaning of the provisions cited by the court of appeals, however, FDA's role is not confined to determining whether the product is unsafe as that term is most commonly used. FDA also generally weighs the risk presented by a product against countervailing health benefits. That balancing of risks and benefits is expressly required when FDA classifies devices into regulatory categories. 21 U.S.C.

⁶ See 21 U.S.C. 393(b)(2)(B) and (C) (Supp. III 1997) (FDA shall protect the public health by ensuring that "drugs are safe and effective," and that "there is a reasonable assurance of the safety and effectiveness of devices."); 21 U.S.C. 360j(e)(1) (FDA "may by regulation require that a device be restricted to sale, distribution, or use * * * upon such * * * conditions as [FDA] may prescribe by regulation, if, because of its potentiality for harmful effect * * *, [FDA] determines that there cannot otherwise be reasonable assurance of its safety and effectiveness."); 21 U.S.C. 355(a) and (d) (No person may introduce any "new drug" absent FDA approval, and, if FDA finds that the drug "is unsafe for use," it "shall issue an order refusing to approve the application."); 21 U.S.C. 331(a), 352(j) (The introduction of a "misbranded" drug or device is prohibited, and a drug or device is "misbranded" when "it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling."); 21 U.S.C. 360c (FDA must classify devices into one of three categories based on what controls are necessary to provide a reasonable assurance of the safety and effectiveness of the device.); 21 U.S.C. 360h(e)(1) (If FDA "finds that there is a reasonable probability that a device * * * would cause serious, adverse health consequences or death," FDA "shall issue an order requiring the appropriate person * * * to immediately cease distribution of such device.").

360c(a)(2)(C) ("the safety and effectiveness of a device are to be determined by weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use"). FDA also follows the same general balancing approach in applying and enforcing other provisions of the Act. See *United States v. Rutherford*, 442 U.S. 544, 555 (1979). For example, as FDA has explained, several products used in the treatment of cancer are highly toxic and therefore are not "safe" as that term is most commonly understood. 61 Fed. Reg. at 44,413. FDA has nonetheless approved such products for use in cancer treatment after finding that the danger of not treating the cancer outweighs the risks of the drugs. *Ibid.*

FDA applied a similar analysis here. It found that, while "tobacco products are unsafe as that term is conventionally understood," the Act contemplates "consideration of not only the risks presented by a product but also any of the countervailing effects of use of that product, including the consequences of not permitting the product to be marketed." 61 Fed. Reg. at 44,412-44,413. After undertaking that balancing process, FDA concluded that, with respect to adults, "the sudden withdrawal from the market of products to which so many millions of people are addicted would be dangerous" for several reasons. *Id.* at 44,413. First, as a result of withdrawal symptoms, "[t]here could be significant health risks to many of these individuals." *Ibid.* Second, the health care system could be "overwhelmed by the treatment demands that these people would create, and it is unlikely that the pharmaceuticals available could successfully treat the withdrawal symptoms of many tobacco users." *Ibid.* Finally, because of the strength of the addiction and the difficulty of quitting, "a black market and smuggling would develop to supply smokers with these products," and the black market products would likely "be even more dangerous than those currently marketed, in that they could con-

tain even higher levels of tar, nicotine, and toxic additives." *Ibid.* FDA therefore reasonably concluded that, "on balance, an approach that prohibits the sale and promotion of cigarettes and smokeless tobacco to children and adolescents, while permitting the sale to adults seems most appropriate, * * * is consistent with the statutory standard of reasonable assurance of safety[,] and is more effective in achieving public health goals than a ban on all tobacco products." *Ibid.*

The Fourth Circuit rejected FDA's analysis on the ground that FDA had applied the wrong legal standard for determining the safety of a product. In the court's view, the Act requires FDA "to strike a balance between the risks and benefits of the *use* of a product, not to weigh the risks of leaving a product on the market against the risks of taking a product off the market." Pet. App. 21a. The statutory text, however, does not impose any such limitation on the agency's discretion. The "benefit to health from the use" of a product, 21 U.S.C. 360c(a)(2)(C), readily encompasses the prevention of the harmful health consequences that would ensue if a product were removed from the market. Tobacco products thus "benefit" the "health" of many users because they relieve otherwise untreatable symptoms of nicotine withdrawal, and because they are safer than black market products that would predictably be used for that purpose if tobacco products could no longer be lawfully marketed to adults.

FDA's interpretation, moreover, best comports with the public health purposes of the Act. From a public health perspective, it would make no sense to require removal of a product from the market when that would cause more harmful health consequences than leaving the product on the market. This Court's decision in *Rutherford* also supports FDA's interpretation. There, the Court affirmed FDA's conclusion that laetrile, while inherently harmless, was unsafe

within the meaning of the Act and should be removed from the market, because its availability could lead persons to reject more beneficial conventional treatments. 442 U.S. at 556. FDA's conclusion here—that the continued marketing of tobacco products to adults should be allowed because their removal could leave those users without treatment alternatives for their addiction and lead them to use more dangerous products—is the mirror image of the analysis approved in *Rutherford*. Thus, FDA's conclusion that the Act does not require tobacco products to be banned is based on a reasonable construction of the Act. Under *Chevron*, the court of appeals should have deferred to it. The court of appeals, however, did not even advert to the question of *Chevron* deference when it rejected FDA's conclusion that the Act does not require it to impose a complete ban on tobacco products. See Pet. App. 20a-30a.

2. Even assuming the regulatory provisions of the Act would require tobacco products to be banned, however, that would not affect the reasonableness of FDA's conclusion that tobacco products are drugs and devices within the meaning of the Act. As Judge Hall stated in his dissent in this case, “[h]ow the FDA has chosen to regulate tobacco has no bearing on the question of *whether* that agency has the authority to regulate it at all.” Pet. App. 60a-61a. See also *Bacto-Unidisk*, 394 U.S. at 792 (while the parties have debated the wisdom of subjecting antibiotic sensitivity disks to premarket review, the only relevant inquiry “is whether the statute’s definition of ‘drug’ authorizes the disc regulations contested here”).

The court of appeals’ contrary conclusion rests on the premise that a ban on tobacco products would be a consequence that the enacting Congress did not contemplate and that therefore would conflict with Congress’s intent, so that, if the regulatory provisions of the Act would require tobacco products to be banned, they cannot be drugs or devices. No

provision of the Act as passed in 1938, however, suggests that a ban on the sale of tobacco products, or indeed any other products—based on powerful evidence that might later came to light establishing the addictive and other intended pharmacological effects of such products—would conflict with congressional intent. Nor is there any other sound basis for reaching that conclusion.

Congress expresses its operative intent in the text of the laws it enacts, see *Oncale*, 523 U.S. at 79-80; *H.J. Inc.*, 492 U.S. at 248, and that intent is not difficult to discern here: When FDA finds that a product is “intended to affect the structure or any function of the body”, 21 U.S.C. 321(g)(1)(C) and (h)(3), and that the product is not sufficiently, “safe,” 21 U.S.C. 393(b)(2)(B) and (C)—*i.e.*, the risks of the product outweigh its benefits—Congress intended for the product not to be marketed.⁷

If this Court were to overturn FDA’s judgment that the risks of tobacco products are outweighed by the countervailing benefits of continued marketing to adults, that would simply mean that the Act, as presently written, requires tobacco products to be banned. That consequence, however, would in no way undermine FDA’s conclusion that tobacco products are intended to affect the structure or function of the body and are therefore drugs and devices subject to regulation under the Act. In those circumstances, then, it would properly be for Congress, after weighing the competing considerations, to decide whether the ban that was

⁷ What is dispositive for purposes of statutory construction is the statute itself, not whether the Congress that enacted the statute could have anticipated a specific application of the general standards that it prescribed, or whether that Congress would have desired the particular consequences of one such natural application. “It is not for us to speculate, much less act, on whether Congress would have altered its stance had the specific events of this case been anticipated.” *TVA v. Hill*, 437 U.S. 153, 185 (1978); accord *Busic v. United States*, 446 U.S. 398, 404-405 (1980).

(by hypothesis) required by the Act in its current form should remain in effect, or whether the Act should be amended to permit the continued marketing of cigarettes and other tobacco products, under whatever conditions Congress might then prescribe. That result would not be at all anomalous in the working of a comprehensive, prophylactic statute designed to protect the public health and safety. It is, for example, the way in which the Food, Drug, and Cosmetic Act itself operated and Congress responded after FDA concluded that saccharin is an animal carcinogen, the continued sale of which as a food additive would be unlawful under the Act, a conclusion that was dictated by the Delaney Clause, 21 U.S.C. 348(c)(3). Congress enacted legislation that imposed an 18-month moratorium on FDA's proposed rule. Saccharin Study and Labeling Act, Pub. L. No. 95-203, 91 Stat. 1451.⁸ That moratorium has been extended repeatedly,

⁸ The court of appeals concluded that FDA's regulatory scheme does not comport with three other provisions of the Act. Those additional criticisms are also misguided. FDA's determination that the "primary mode" of tobacco products is that of a "drug" does not mean that FDA must regulate tobacco products as drugs rather than devices. Pet. App. 24a. A finding concerning the primary mode of a combination product only determines which component of FDA will have principal responsibility to conduct premarket review. See 21 U.S.C. 353(g)(1). Regardless of which component has that responsibility, FDA may regulate a combination product by using its authority to regulate drugs, its authority to regulate devices, or both. 61 Fed. Reg. at 44,400-44,403. Nor does 21 U.S.C. 352(f)(1) automatically require tobacco manufacturers to include directions for use on their product labels. Pet. App. 25a-26a. FDA may grant an exemption from that requirement when the information is "not necessary for the protection of public health." 21 U.S.C. 352(f)(1). Because the way in which tobacco products are used is common knowledge, FDA reasonably determined that an exemption was appropriate. 61 Fed. Reg. at 44,465. Finally, 21 U.S.C. 352(f)(2) does not require tobacco manufacturers to include additional warnings for children on the labels of tobacco products. Pet. App. 26a-27a. FDA reasonably concluded that the familiar Surgeon General's warnings required by other federal statutes are sufficient to

and it remains in effect today. See Pub. L. No. 104-180, § 602, 110 Stat. 1594; 21 U.S.C. 348 note.⁹

D. FDA's Prior Statements, Unenacted Tobacco Bills, And Certain Tobacco-Specific Statutes Enacted Long After 1938 Do Not Detract From The Reasonableness Of FDA's Interpretation

In rejecting FDA's conclusion that tobacco products are drugs and devices, the court of appeals also relied on FDA's prior statements concerning its authority to regulate tobacco products, unenacted bills that would have specifically authorized FDA to regulate tobacco products, and certain tobacco-specific statutes enacted long after the Federal Food, Drug, and Cosmetic Act was passed. FDA carefully examined each of those sources and reasonably determined that they do not detract from the conclusion that tobacco products are drugs and devices under the Act.

1. Until FDA issued the regulations at issue here, the only instances in which the agency had found that tobacco products were drugs involved cases in which there were express market claims of therapeutic value. FDA's prior position on the subject was authoritatively expressed in decisions in 1977 and 1980 rejecting petitions filed by Action

satisfy that provision's requirement that a label bear adequate warnings against use by children. 61 Fed. Reg. at 44,465. In any event, as discussed above, the sole question presented here is whether tobacco products are drugs and devices within the meaning of the Act. Whether FDA is required to take *further* steps, in addition to the regulations it has prescribed, does not have any bearing on the resolution of that question.

⁹ Congress responded in a similar manner to the holding in *TVA v. Hill*, 437 U.S. 153 (1978), that the Endangered Species Act of 1973 (ESA), 16 U.S.C. 1531 *et seq.*, prohibited the completion of the Tellico Dam because the project would destroy the snail darter, by directing the completion of the dam, "notwithstanding" the ESA. See Energy and Water Development Appropriation Act, Pub. L. No. 96-69, 93 Stat. 449. See also *County of Oneida v. Oneida Indian Nation*, 470 U.S. 226, 253 (1985).

on Smoking in Health (ASH) to regulate cigarettes as drugs or devices. See J.A. 44-49 (Letter from FDA Commissioner Kennedy to ASH Executive Director Banzhaf (Dec. 5, 1977)); J.A. 50-68 (Letter from FDA Commissioner Goyan to ASH Executive Director Banzhaf (Nov. 25, 1980)). Focusing on those decisions, and some earlier statements made by FDA officials, the court of appeals treated FDA's current position as not warranting deference. Pet. App. 31a-37a. The court of appeals erred both in its understanding of FDA's prior position and in its approach to reviewing FDA's current regulation of tobacco products.

An agency's position on any given issue is not "carved in stone." *Chevron*, 467 U.S. at 863. To fulfill its assigned responsibilities, an agency "must be given ample latitude to 'adapt [its] rules and policies to the demands of changing circumstances,'" *Motor Vehicle Mfrs. Ass'n v. State Farm Mut.*, 463 U.S. 29, 42 (1983), and "must consider varying interpretations and the wisdom of its policy on a continuing basis." *Chevron*, 467 U.S. at 863-864. For those reasons, and because "the whole point of *Chevron* is to leave the discretion provided by the ambiguities of a statute with the implementing agency," *Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. 735, 742 (1996), an agency is always free to change its position on an issue or its interpretation of a statute, as long as it offers a "reasoned analysis" that justifies the change. *Rust v. Sullivan*, 500 U.S. 173, 187 (1991); *Chevron*, 467 U.S. at 863-864; *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 42.

FDA provided such a "reasoned analysis" here. Specifically, FDA explained that three key developments led to its change in position. *First*, while no major health organization had determined that nicotine was an addictive drug before 1980, by 1994, every leading scientific panel or organization had concluded that nicotine is addictive. 61 Fed. Reg. at 45,228. *Second*, since 1980, scientific evidence has shown

that an overwhelming percentage of users of tobacco products do so to satisfy their addiction and to obtain nicotine's mood-altering effects. *Id.* at 45,233-45,234. In contrast, before 1980, there was no evidence regarding the proportion of users who were addicted, and the evidence was insufficient to conclude that tobacco products were consumed primarily for their pharmacological effects. *Id.* at 45,234-45,235. *Third*, recently released internal industry documents show that tobacco manufacturers have long known that consumers use tobacco products to sustain addiction and for other pharmacological effects, and that manufacturers have deliberately engineered their products to deliver active doses of nicotine. *Id.* at 45,235-45,236. Almost none of that evidence was publicly available in 1980. *Id.* at 45,237. FDA's finding that tobacco products are intended to affect the structure and function of the body, regardless of whether they are accompanied by express market claims of therapeutic value, is therefore "based on an overwhelming body of new evidence that ha[d] become available since FDA last considered this issue." *Id.* at 45,237. Because FDA provided a reasoned explanation for its change in position, that position is entitled to full *Chevron* deference. *Rust*, 500 U.S. at 186-187; *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 42; see also *Smiley*, 517 U.S. at 742.

The court of appeals concluded that FDA's prior decisions not to regulate tobacco products were based on a categorical view that tobacco products cannot be subject to regulation under the Act absent specific health claims, rather than the absence of the kind of evidence of intended effects discussed above. Pet. App. 36a. The court's understanding of the ASH decisions is incorrect. In the 1977 decision, FDA rejected ASH's assertion that cigarettes could be regulated as drugs because consumers use them for their effects on the body, on the ground that ASH's evidence was not sufficient to establish such an intent by the manufacturers or vendors of ciga-

rettes. J.A. 48-49. The government's brief defending FDA's decision in the court of appeals explained that FDA had concluded that cigarettes could not be regulated as drugs "in the absence of health claims by the manufacturers or vendors or other evidence of the manufacturers' or vendors' intent to affect the bodily structure or functions." Gov't Br. at 14, *Action on Smoking & Health v. Harris*, 655 F.2d 236 (D.C. Cir. 1980) (emphasis added). In affirming FDA's decision, the D.C. Circuit stated that "we do not read [FDA's decision] to mean either that the Commissioner will never consider evidence of consumer intent on this question or that he simply ignored the evidence presented to him in this petition." *ASH*, 655 F.2d at 239. Instead, the petition failed because *ASH* had failed to "meet the high standard established in cases where the statutory 'intent' is derived from consumer use alone." *Ibid.*

In the 1980 "device" decision, FDA stated that the relevant inquiry under the Act is whether there "is objective evidence that the manufacturer or vendor intends that the article is to affect the structure or a function of the body." J.A. 56. FDA further explained that a finding of such an intent could be based not only on a manufacturer's market claims, but also on "the circumstances surrounding [a product's] distribution," and the "consumer intent in using a product." *Ibid.* FDA determined, however, that *ASH*'s evidence, including *ASH*'s evidence of consumer use, "fails to establish that cigarettes are intended 'to affect the structure or any function of the body.'" J.A. 57; accord J.A. 61-63. FDA's prior rulings on formal petitions to regulate tobacco products therefore rested on the absence of sufficient evidence at the time that such products were intended to affect the structure or function of the body—not on a categorical view that tobacco products can satisfy the drug and device

definitions only if manufacturers make express market claims of therapeutic value.¹⁰

Even if FDA's prior decisions not to regulate tobacco products could be understood as resting on such a categorical view, however, that would not affect the validity of FDA's

¹⁰ The court of appeals also relied upon a 1914 opinion letter by FDA's predecessor agency. Pet. App. 32a. That letter, however, *supports* the proposition that labeling claims are not dispositive and that consumer use is relevant to the question of "intent":

Under the Food and Drugs Act, a drug is defined as any substance, or mixture of substances, intended to be used for the cure, mitigation, or prevention of disease of either man or other animals. It, therefore, follows that tobacco and its preparations, when labeled in such a manner as to indicate their use for the cure, mitigation, or prevention of disease, are drugs within the meaning of the act, and, as such, are subject to the provisions thereof.

On the other hand, tobacco and its preparations which are not so labeled and are used for smoking or chewing or as snuff and not for medicinal purposes are not subject to the provisions of the act.

USDA Bureau of Chemistry, 13 Service and Regulatory Announcements 24 (Apr. 1914) (Feb. 1914 Announcements ¶ 13, Opinion of Chief of Bureau C.L. Alsberg). As the letter makes clear, labeling can be *sufficient* to establish the requisite intent. But if the absence of labeling were sufficient to negate intent, the italicized ("and are used") clause would have been superfluous. The final sentence of the opinion simply states that tobacco products could escape regulation under the 1906 Act as drugs if they were not labeled to indicate their use for the cure, mitigation, or prevention of disease *and* they were not used for such purposes. See 61 Fed. Reg. at 45,222 n.1160.

The court of appeals also relied on letters or statements by FDA officials to Members of Congress during hearings at various times after the Act was passed in 1938, to the effect that FDA did not have authority to regulate tobacco products as customarily marketed. See, e.g., Pet. App. 32a-34a. Those statements are best understood as reflecting FDA's view on those occasions that there was insufficient evidence that tobacco products as customarily marketed were intended to affect the structure or any function of the body.

present determination that tobacco products are drugs and devices under the Act. An agency is not only free to alter its view of the underlying facts; it is also free to change its view of the appropriate legal standard for evaluating the facts. See *Rust*, 500 U.S. at 186-187. Regardless of whatever uncertainty there might have been about FDA's position in the past, FDA has now unambiguously concluded that the drug and device definitions encompass products that are intended by manufacturers to affect the structure or function of the body, irrespective of whether the manufacturer makes express claims of therapeutic value. FDA has also concluded that there is no basis for creating an exception to that legal standard for tobacco products. Because that interpretation of the Act is supported by a "reasoned analysis," it is entitled to full *Chevron* deference. *Ibid.*

2. Over the years, Congress has failed to enact bills that would have expressly authorized FDA to regulate tobacco products. The court of appeals viewed such congressional inaction as strong evidence that FDA lacks authority to regulate tobacco products under the Act. Pet. App. 37a-39a. Failed legislative proposals, however, do not furnish a sound basis for determining the meaning of a prior statute. See, e.g., *United States v. Estate of Romani*, 523 U.S. 517, 533-535 (1998); *Central Bank v. First Interstate Bank*, 511 U.S. 164, 187 (1994). The Constitution requires Congress to express its will through enacted legislation, not unenacted bills. *INS v. Chadha*, 462 U.S. 919, 945-959 (1983). Congressional inaction also "lacks persuasive significance because several equally tenable inferences may be drawn from such inaction, including the inference that the existing legislation already incorporated the offered change." *Central Bank*, 511 U.S. at 187 (quoting *Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 650 (1990)). For those reasons, Congress's failure to enact bills that would have expressly authorized FDA to regulate tobacco products has no more bearing on the

question presented in this case than does Congress's failure to enact bills that would have excluded tobacco products from the reach of the Act, e.g., S. Rep. No. 1295, 104th Cong., 1st Sess. (1995); H.R. Rep. No. 2283, 104th Cong., 1st Sess. (1995), or Congress's failure during the past three years to overturn FDA's decision to regulate tobacco products.

The court of appeals' reason for attributing significance to the legislative inaction at issue here is particularly unconvincing. In the court's view, such inaction amounted to congressional "ratification" of FDA's prior statements and decisions that tobacco products are not subject to regulation under the Act. Pet. App. 37a. As we have explained, however, FDA's prior position was based on the absence of sufficient evidence showing that tobacco products were intended by manufacturers to affect the structure or any function of the body. Ratification of that position would not reflect any congressional view on whether tobacco products would be covered by the Act if new evidence established that they *are* intended by manufacturers to be used for sustaining addiction and for sedation, stimulation, and weight control.

More fundamentally, congressional inaction can never affect the authority of an agency under *Chevron* to alter its position on an issue. *Motor Vehicle Manufacturers Ass'n, supra*, is controlling on that point. In that case, the Court held that Congress's failure to overturn an agency regulation did not affect the scope of the agency's authority to rescind the regulation. 463 U.S. at 44-45. The Court explained that the standard for reviewing agency action is not "enlarged or diminished by subsequent congressional action," and that "even an unequivocal ratification—short of statutory incorporation—* * * would not connote approval or disapproval of an agency's later decision to rescind the regulation." *Id.* at 45. Under the analysis in *Motor Vehicle Manufacturers Ass'n*, Congress's failure to overturn FDA's prior position

has no bearing on the validity of FDA's present position that tobacco products are drugs or devices under the Act.

3. Since the Surgeon General issued his well-known report in 1964, Congress has enacted several statutes that deal with tobacco products in certain specific respects. See Pet. App. 39a-42a. None of the statutes, however, expressly exempts tobacco products from the reach of the Act. Nor is there any irreconcilable conflict between the subsequent statutes and the conclusion that tobacco products fall within the reach of the Act. *TVA*, 437 U.S. at 189-190 (implied repeal occurs only when there is an irreconcilable conflict between the old and the new laws). Those statutes therefore do not affect the reasonableness of FDA's conclusion that tobacco products are drugs and devices under the Act.

a. The Federal Cigarette Labeling and Advertising Act (FCLAA), 15 U.S.C. 1331 *et seq.*, requires cigarette packaging and advertising to bear specific warnings from the Surgeon General concerning the adverse health effects of smoking. 15 U.S.C. 1333. FCLAA also contains a specific preemption section that provides that "[n]o statement relating to smoking and health, other than the statement required by section 1333 * * *, shall be required on any cigarette package." 15 U.S.C. 1334(a). That statutory text makes clear that FDA may not require warning labels on cigarettes that are different from those required by FCLAA. The text of FCLAA does not remotely suggest, however, that it altogether deprives FDA of any authority to regulate tobacco products. As this Court explained in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992), FCLAA "merely prohibit[s] state and federal rulemaking bodies from mandating particular cautionary statements on cigarette labels."

The court of appeals derived a broader preemptive scope from FCLAA's statement of policy, which is, *inter alia*, "to establish a comprehensive Federal program to deal with

cigarette labeling and advertising with respect to any relationship between smoking and health, whereby * * * commerce and the national economy may be protected to the maximum extent consistent with this declared policy and * * * not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health." 15 U.S.C. 1331. From that statement, the court concluded that Congress had a broad purpose to protect the national economy by allowing the continued marketing of cigarettes if the packages bear sufficient warning labels—a goal the court believed would be undermined if tobacco products were "drugs" and "devices" subject to regulation under the Act. Pet. App. 43a-44a.

As we have already explained, however, treatment of tobacco products as drugs or devices does not lead to the conclusion that such products must be banned, and the regulations at issue here permit the continued sale of tobacco products to adults. In any event, FCLAA does not seek to protect the national economy by shielding tobacco products from laws that would restrict their marketing. Instead, as the text of FCLAA's policy statement makes clear, and as its narrow preemption provision confirms, Congress's goal was far more limited: It wanted to "protect[] the national economy from the burden imposed by diverse, nonuniform, and confusing cigarette labeling and advertising regulations." *Cipollone*, 505 U.S. at 514; see *Banzhaf v. FCC*, 405 F.2d 1082, 1089 (D.C. Cir. 1968) ("[n]othing in the [FCLAA] Act indicates that Congress had any intent at all with respect to other types of regulation by other agencies—much less that it specifically meant to foreclose all such regulation"), cert. denied, 396 U.S. 842 (1969). FCLAA does not limit the authority of FDA to ban the sale of tobacco products, any more than it limits the authority of a State to do so (as indeed all States have done with respect to sales to minors,

61 Fed. Reg. at 44,441). The enactment of FCLAA therefore does not affect the validity of FDA's conclusion that tobacco products are drugs and devices under the Act.

b. The Comprehensive Smokeless Tobacco Health Education Act of 1986 (Smokeless Tobacco Act), 15 U.S.C. 4401 *et seq.*, requires warnings on smokeless tobacco packages that are similar to the warnings required on cigarette packages. 15 U.S.C. 4402(a) and (b). It also contains a similar express preemption provision, which states: "No statement relating to the use of smokeless tobacco products and health, other than the statements required by section 4402 of this title, shall be required by any Federal agency to appear on any package or in any advertisement." 15 U.S.C. 4406(a). Like FCCLA, the Smokeless Tobacco Act simply requires certain warning labels on packages and precludes federal agencies, including FDA, from requiring different ones. Like FCCLA, the Smokeless Tobacco Act does not in any way suggest that tobacco products cannot be drugs or devices under the Act.

c. The Alcohol and Drug Abuse Amendments of 1983, Pub. L. No. 98-24, 97 Stat. 178, 42 U.S.C. 290aa *et seq.*, direct the Secretary of Health and Human Services to report to Congress every three years on "the health consequences * * * of drug abuse in the United States [and] * * * current research findings made with respect to drug abuse, including current findings on * * * the addictive property of tobacco," and to include the Secretary's recommendations for "legislation and administrative action as the Secretary may deem appropriate." 42 U.S.C. 290aa-2(b). Those reporting requirements do not conflict with FDA's conclusion that tobacco products are drugs and devices under the Federal Food, Drug, and Cosmetic Act. As Judge Hall explained, the reporting obligations do no more than acknowledge the important role that the Secretary has in determining policy in the complex field of drug abuse, and require the Secretary

"to ask Congress for any *additional* tools * * * needed to * * * perform that role effectively." Pet. App. 69a.

d. The Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act (ADAMHA), Pub. L. No. 102-321, 106 Stat. 394, created separate block grants for state mental health services and drug and alcohol abuse programs. One condition for receiving a block grant is that a State must have in effect a law making it illegal to sell or distribute tobacco products to children under age 18. 42 U.S.C. 300x-26(a). Neither the ADAMHA as a whole nor that specific requirement implies that FDA has no authority to regulate tobacco products as a drug or a device.

The court of appeals concluded that, if tobacco products are "drugs" or "devices" subject to regulations under the Federal Food, Drug, and Cosmetic Act, then one provision of that Act, 21 U.S.C. 360k(a) "would prohibit States from addressing the problem of youth access," in conflict with the congressional intent evident in ADAMHA. Pet. App. 51a. Under Section 360k(a), a State may not establish "any requirement" with respect to devices that is "different from, or in addition to, any requirement applicable under" the Act. 21 U.S.C. 360k(a)(1). Section 360k(a), however, "does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496-497 (1996) (quoting 21 C.F.R. 808.1(d)(2)). Since ADAMHA's "age 18" restriction is the same as the access restriction imposed by FDA's regulations, the regulations will not prevent States from complying with their block grant obligations under ADAMHA. In fact, by providing an additional level of enforcement against the sale of tobacco products to children, the regulations will "facilitate the end result that Congress sought" in ADAMHA. 61 Fed. Reg. at 44,547.

FDA's regulations could potentially preempt state regulations that impose stricter conditions on the sale of tobacco

products than those set forth in the regulations. But that result does not suggest that there is any inherent or irreconcilable conflict between ADAMHA and FDA's conclusion that tobacco products are covered under the Federal Food, Drug, and Cosmetic Act. ADAMHA does not provide a protective shield for all state regulations of tobacco. It simply establishes one condition for receiving a block grant, and, as noted above, FDA's regulations do not prevent States from complying with that condition. In any event, under 21 U.S.C. 360k(b), States may apply for an exemption from the preemptive force of the Act, and FDA has substantial discretion to grant such an exemption. See 61 Fed. Reg. at 44,550; *Medtronic*, 518 U.S. at 482 n.5, 496. Thus, like the other later-enacted statutes, ADAMHA does not impose any impediment to FDA's thoroughly documented and reasoned conclusion that tobacco products are "drugs" and "devices" within the meaning of the Federal Food, Drug, and Cosmetic Act.

CONCLUSION

The judgment of the court of appeals should be reversed.
Respectfully submitted.

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APPENDIX

1. 21 U.S.C. 321(g)(1) provides as follows:

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

2. 21 U.S.C. 321(h) provides as follows:

(h) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

3. 21 U.S.C. 352(f) and 352(j) provide as follows:

§ 352. Misbranded drugs and devices.

A drug or device shall be deemed to be misbranded—

* * * * *

(f) Directions for use and warnings on label

Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or

device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

* * * * *

(j) Health-endangering when used as prescribed

If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

4. 21 U.S.C. 353(g) provides as follows:

(g) Regulation of combination products

(1) The Secretary shall designate a component of the Food and Drug Administration to regulate products that constitute a combination of a drug, device, or biological product. The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

(A) a drug (other than a biological product), the persons charged with premarket review of drugs shall have primary jurisdiction,

(B) a device, the persons charged with premarket review of devices shall have primary jurisdiction, or

(C) a biological product, the persons charged with premarket review of biological products shall have primary jurisdiction.

5. 21 U.S.C. 355(a) provides as follows:

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

6. 21 U.S.C. 355(d) provides in relevant part as follows:

(d) Grounds for refusing application; approval of application; "substantial evidence" defined

If the Secretary finds, after due notice to the applicant in accordance with subsection (c) of this section and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b) of this section, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; * * * (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; * * * he shall issue an order refusing to approve the application.
* * *

7. 21 U.S.C. 360c(a) provides as follows:

§ 360c. Classification of devices intended for human use

(a) Classes of devices

(1) There are established the following classes of devices intended for human use:

(A) Class I, GENERAL CONTROLS.—

(i) A device for which the controls authorized by or under section 351, 352, 360, 360f, 360h, 360i, or 360j of this title or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but because it—

(I) is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and

(II) does not present a potential unreasonable risk of illness or injury,

is to be regulated by the controls referred to in clause (i).

(B) Class II, SPECIAL CONTROLS.—A device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, post-market surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 360(k) of this title), recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance. For a device that is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.

(C) Class III, PREMARKET APPROVAL.—A device which because—

(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and

(ii)(I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or

(II) presents a potential unreasonable risk of illness or injury,

is to be subject, in accordance with section 360e of this title, to premarket approval to provide reasonable assurance of its safety and effectiveness.

If there is not sufficient information to establish a performance standard for a device to provide reasonable assurance of its safety and effectiveness, the Secretary may conduct such activities as may be necessary to develop or obtain such information.

(2) For purposes of this section and sections 360d and 360e of this title, the safety and effectiveness of a device are to be determined—

(A) with respect to the persons for whose use the device is represented or intended,

(B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and

(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

8. 21 U.S.C. 360c(d)(1) provides as follows:

(d) Panel recommendation; publication; priorities

(1) Upon receipt of a recommendation from a panel respecting a device, the Secretary shall publish in the Federal Register the panel's recommendation and a proposed regulation classifying such device and shall provide interested persons an opportunity to submit comments on such recommendation and the proposed regulation. After reviewing such comments, the Secretary shall, subject to paragraph (2), by regulation classify such device.

9. 21 U.S.C. 360f(a) provides as follows:

§ 360f. Banned devices

(a) General rule

Whenever the Secretary finds, on the basis of all available data and information that—

(1) a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury; and

(2) in the case of substantial deception or an unreasonable and substantial risk of illness or injury which the Secretary determined could be corrected or eliminated by labeling or change in labeling and with respect to which the Secretary provided written notice to the manufacturer specifying the deception or risk of illness or injury, the labeling or change in labeling to correct the

deception or eliminate or reduce such risk, and the period within which such labeling or change in labeling was to be done, such labeling or change in labeling was not done within such period;

he may initiate a proceeding to promulgate a regulation to make such device a banned device.

10. 21 U.S.C. 360h(e)(1) provides as follows:

(e) Recall authority

(1) If the Secretary finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the device)—

(A) to immediately cease distribution of such device, and

(B) to immediately notify health professionals and device user facilities of the order and to instruct such professionals and facilities to cease use of such device.

* * * * *

11. 21 U.S.C. 360j(e) provides as follows:

(e) Restricted devices

(1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use—

(A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or

(B) upon such other conditions as the Secretary may prescribe in such regulation,

if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. No condition prescribed under subparagraph (B) may restrict the use of a device to persons with specific training or experience in its use or to persons for use in certain facilities unless the Secretary determines that such a restriction is required for the safe and effective use of the device. No such condition may exclude a person from using a device solely because the person does not have the training or experience to make him eligible for certification by a certifying board recognized by the American Board of Medical Specialties or has not been certified by such a Board. A device subject to a regulation under this subsection is a restricted device.

(2) The label of a restricted device shall bear such appropriate statements of the restrictions required by a regulation under paragraph (1) as the Secretary may in such regulation prescribe.

12. 21 U.S.C. 360k provides as follows:

§ 360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

13. 21 U.S.C. 371(a) provides as follows:

§ 371. Regulations and hearings

(a) Authority to promulgate regulations

The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.

14. 21 U.S.C. 393(a) & (b) provide as follows:

§ 393. Food and Drug Administration

(a) In general

There is established in the Department of Health and Human Services the Food and Drug Administration (hereinafter in this section referred to as the "Administration").

(b) Mission

The Administration shall—

(1) promote the public health by promptly and efficiently reviewing clinical research and

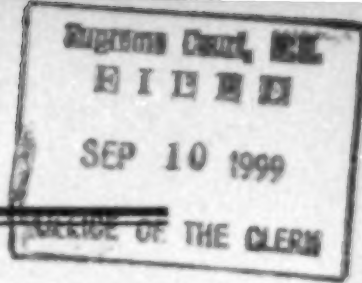
taking appropriate action on the marketing of regulated products in a timely manner;

(2) with respect to such products, protect the public health by ensuring that—

* * * * *

(B) human and veterinary drugs are safe and effective;

(C) there is reasonable assurance of the safety and effectiveness of devices intended for human use
* * *.



IN THE
Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, *et al.*,
Petitioners,
v.

BROWN AND WILLIAMSON TOBACCO CORP., *et al.*,
Respondents.

On Writ of Certiorari to the
United States Court of Appeals
for the Fourth Circuit

**BRIEF FOR RESPONDENT
R.J. REYNOLDS TOBACCO COMPANY**

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R.J. Reynolds Tobacco Company

QUESTION PRESENTED

Whether the Food and Drug Administration ("FDA") has jurisdiction to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act ("FDCA") as "drugs" and medical "devices" even though (1) FDA's theories for categorizing tobacco products as drugs and devices are unprecedented, would make many medically important drugs and devices unlawful, and would expand FDA's jurisdiction far beyond Congress's intent; (2) Congress has enacted a series of tobacco-specific statutes, which establish the congressional policy and program for regulation of tobacco products with respect to health, advertising, and underage access, and give FDA no role; (3) the tobacco-specific statutes are premised on the continued marketing of tobacco products with specified warnings, but the FDCA would require that tobacco products be banned; and (4) regulation of tobacco products as devices would oust the States from the lead role in regulating local retail sales of tobacco products?

RULE 29.6 LISTING

Pursuant to Supreme Court Rule 29.6, Respondent submits the following corporate information:

The parent company of R.J. Reynolds Tobacco Company is R.J. Reynolds Tobacco Holdings, Inc. R.J. Reynolds Tobacco Company has no nonwholly owned subsidiaries.

The corporate transactions referred to in the Rule 29.6 listing in Respondents' Brief in Opposition to Petition for a Writ of Certiorari have been completed. The international tobacco business of R.J. Reynolds Tobacco Company was sold to Japan Tobacco, Inc.; and R.J. Reynolds Tobacco Company was separated from its former parent company, RJR Nabisco Holdings Corp., by a stock spin-off.

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SAMHSA, <i>Synar Regulation Implementation FY 97 State Compliance</i> (undated)	46
U.S. Dep't of HEW, <i>Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service</i> (1964)	37
Webster's <i>Seventh New Collegiate Dictionary</i> 170-71 (1965)	38

**BRIEF FOR RESPONDENT
R.J. REYNOLDS TOBACCO COMPANY**

OPINIONS BELOW

The opinions below are identified in Brief for Petitioners ("Pet. Br.") 1.

JURISDICTION

The basis for this Court's jurisdiction is set forth at Pet. Br. 1.

**STATUTORY AND REGULATORY
PROVISIONS INVOLVED**

The Brief for Petitioners fails to list the Federal Cigarette Labeling and Advertising Act, the Comprehensive Smokeless Tobacco Health Education Act of 1986, the ADAMHA Reorganization Act ("ADAMHA Amendments"), and other tobacco-specific statutes, which are set forth in Appendix to Respondents' Brief in Opposition to Petition for a Writ of Certiorari ("Opp. Cert. App.").

STATEMENT¹

This case is about who has the power to make national policy for the regulation of tobacco products.² Federal statutes specifically addressed to tobacco already state

¹ Lodged with the Court is a compilation of all materials cited herein, except published judicial decisions, statutes, regulations, *Federal Register* documents, the 1964 Surgeon General's report on smoking and health, and briefs and appendices herein.

² FDA's assertion of jurisdiction relates to cigarettes and smokeless tobacco products. See 21 C.F.R. § 897.1(a) (1999). All references herein to "tobacco products" are to cigarettes and smokeless tobacco products "as customarily marketed." The words "as customarily marketed" are FDA's. See Letter from Mark Novitch for Comm'r Jere Goyan to John F. Banzhaf, III, and Peter N. Georgiades (Nov. 25, 1980) (FDA Dkt. Nos. 77P-0185, 78P-0338/CP) ("Novitch/Goyan Ltr.") (Joint Appendix ("Jt. App.") 50, 67). Those words refer to the marketing of cigarettes and smokeless tobacco products with the customary claims (e.g., "good taste"), in contrast to claims of a health benefit.

"the policy of the Congress . . . to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health. . . ." 15 U.S.C. § 1331. Because the Food and Drug Administration ("FDA") nevertheless asserts that it has the power to regulate, and ban, tobacco products under the Federal Food, Drug, and Cosmetic Act ("FDCA" or "1938 Act"), Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified, as amended, at 21 U.S.C. §§ 301-97 (1994 & Supp. III 1997)), the issue is whether the FDCA, read together with the tobacco-specific statutes, authorizes FDA to do so.

Until 1995, FDA repeatedly disclaimed authority to regulate tobacco products, even though, throughout this century, they have been widely considered to have harmful effects, *see, e.g., Austin v. State*, 101 Tenn. 563, 566-67, 48 S.W. 305, 306 (1898), *aff'd*, 179 U.S. 343 (1900). In light of FDA's longstanding position, and with a view to the many competing interests relating to tobacco, Congress, starting in 1965, has enacted, *outside the FDCA*, a series of tobacco-specific statutes that provide for the regulation of tobacco products with respect to health, underage access, and related issues. The regulation of tobacco products has been a highly political matter, which Congress has addressed in legislation many times in the last 34 years, without providing any role for FDA. In reaching out now to regulate this large, separate, long-established economic sector it has never regulated before, FDA relies on unprecedented and problematic interpretations of definitional and operative provisions of the FDCA. Those interpretations cause sharp conflicts with the tobacco-specific statutes, and oust the States from the lead role in regulating underage access to tobacco products, despite congressional legislation specifically designed to strengthen the State role.

Since early in this century, tobacco products have been commonly used, and tobacco and tobacco products have constituted a major sector of the U.S. economy. See Opp. Cert. 2-3. Under the Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906) ("1906 Act"), FDA never claimed jurisdiction over them. Nothing in the 1938 Act's text or legislative history suggests that Congress drafted it to grant FDA such jurisdiction or to accommodate potential application to such products.

From 1938 to 1995, FDA repeatedly disclaimed jurisdiction over tobacco products—in formal decisions, in testimony to Congress, and in the routine administration of the FDCA. FDA adhered to that position despite (i) widespread belief that cigarettes are harmful to health, and (ii) scientific knowledge that they have foreseeable effects on the functioning of the body, as reflected in medical and scientific literature and government reports. FDA continued to adhere to it even after (iii) concerns about smoking and health reached the national political agenda in 1964, (iv) concerns about underage smoking led Congress in 1970 to ban cigarette advertising on television and radio, (v) cigarette manufacturers began disclosing tar and nicotine ratings in advertising in the early 1970s, thereby making clear that cigarette designs achieve predictable tar yields (associated with predictable nicotine yields), and (vi) the National Institute on Drug Abuse in 1979 issued a report declaring cigarettes addictive. See Opp. Cert. 4-6, 8, 11.

In 1964-65, Congress, for the first time, fully considered the issue of smoking and health. FDA testified that it had no jurisdiction.³ In light of FDA's position, Congress

³ *Cigarette Labeling and Advertising: Hearings Before the House Comm. on Interstate and Foreign Commerce on Bills Regulating the Labeling and Advertising of Cigarettes and Relating to Health Problems Associated with Smoking*, 88th Cong. 56 (1964) (testimony of Surgeon General Terry) ("1964 Hearings"); *Ciga-*

in 1965 enacted the Federal Cigarette Labeling and Advertising Act ("FCLAA"), Pub. L. No. 89-92, 79 Stat. 282 (1965) (codified, as amended, at 15 U.S.C. §§ 1331-41 (1994)) (Opp. Cert. App. 1a-5a, 55a-68a). Thereafter, in 1970, 1983, 1984, 1986, and 1992, it enacted additional statutes addressing tobacco and health. Opp. Cert. App. 1a-85a, 101a-106a. Thus, Congress has created and actively overseen a separate regulatory program for tobacco and health; and, as new information (of the sort FDA now relies on) has been presented to it, it has enacted additional tobacco-specific statutes.

These statutes provide in a careful and balanced way for the regulation of tobacco products with respect to health and related matters. Congress decided that tobacco products would not be banned but would bear warnings, that advertising them on television and radio would be prohibited, that "the addictive property of tobacco" would be the subject of reports to Congress from the Department of Health and Human Services ("HHS"), that their ingredients would be reviewed by HHS and would also be the subject of reports to Congress from HHS, and that the States would be given financial incentives to enact and effectively enforce restrictions on underage access. None of these regulatory controls is administered by FDA.

Today, these statutes embody Congress's policy and program for the very areas FDA now seeks to regulate differently. Congress's ongoing weighing of the competing interests—including health, federalism, the autonomy of adults, law enforcement, State and regional concerns,

rette Labeling and Advertising—1965: Hearings Before the House Comm. on Interstate and Foreign Commerce, 89th Cong. 193 (1965) (testimony of FDA Dep. Comm'r Rankin) ("1965 Hearings"). FDA did not say to Congress (as it now says, 61 Fed. Reg. 44,396, 45,222 (1996)) that it regulates cigarettes whenever it has evidence that brings them within the FDCA's definitions.

and the national economy—has been an inherently *political* undertaking. The current regulatory system established by the tobacco-specific statutes, together with the absence of FDA jurisdiction over tobacco products sold without therapeutic claims, marks the place where "opposing social and political forces have come to rest." *Chrysler Corp. v. Brown*, 441 U.S. 281, 313 (1979) (quoting prior decisions).

Nevertheless, in 1995 FDA proposed, 60 Fed. Reg. 41,314 (1995), and in 1996 it made final, its own assertion of jurisdiction and regulatory controls over tobacco products, 61 Fed. Reg. 44,396 (1996). It decided that they are both "drugs" and "devices," *id.* at 45,208-16, and that it may selectively apply to them some, but not all, of the FDCA's mandatory provisions that protect consumers with respect to all "drugs" and/or all "devices," *id.* at 44,403-04; 60 Fed. Reg. 41,348-49. On the basis of its study of their health effects, *id.* at 41,318-21, FDA found that tobacco products are "unsafe," and "dangerous," 61 Fed. Reg. 44,412; *see also id.* at 44,405, 44,571; 60 Fed. Reg. 41,349. Previously as well, FDA and HHS had advised Congress that cigarettes cannot satisfy the FDCA's requirement of safety, and that consequently cigarettes could not be marketed under the FDCA.⁴ Now, however, in asserting jurisdiction over tobacco products, FDA abandons its prior understanding that the FDCA precludes the marketing of unsafe drugs and devices.

Although prohibition of alcohol occurred by constitutional amendment, FDA claims that Congress in 1938

⁴ 1964 *Hearings* 18 (Letter from HEW Sec. Anthony Celebrezze to Hon. Oren Harris); *Public Health Cigarette Amendments of 1971: Hearings Before the Consumer Subcomm. of the Senate Comm. on Commerce, 92d Cong. 242 (1972) (testimony of FDA Comm'r Edwards) ("1972 Hearings")*; *Smoking Prevention Education Act: Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 98th Cong. 84 (1983) (Testimony of Ass't Sec. for Health Brandt)*.

gave it discretion to ban tobacco products by administrative action. See 61 Fed. Reg. 44,405, 44,412-13; 60 Fed. Reg. 41,349, 41,523-24. In 1996, it found the question whether to ban them a "close" one, 61 Fed. Reg. 44,416, but explained that, for now, it had rejected a ban because "there could be significant health risks to many" tobacco users, "the health care system [might] be overwhelmed by the treatment demands that these people would create," and a "black market and smuggling would develop" 61 Fed. Reg. 44,413. Thus, FDA's policymaking extended far beyond the effectiveness and safety of medical products.

Accepting FDA's factual findings *arguendo*, respondents moved in the district court for summary judgment on four grounds: (1) that the FDCA does not apply to tobacco products; (2) that, under FDA's findings, tobacco products cannot be either "devices," as distinct from "drugs," or "combination drug/devices," and that FDA does not have discretion to apply to them some mandatory statutory provisions but not others; (3) that FDA's restrictions on tobacco product advertising are not authorized by the FDCA, 21 U.S.C. § 360j(e); and (4) that those restrictions violate the First Amendment. The district court rejected the first two grounds, held that the advertising restrictions are unauthorized, and therefore did not reach the fourth ground. Pet. App. 76a-134.

The court of appeals reversed, with one dissent. It held that "it is clear that Congress did not intend to give the FDA jurisdiction over tobacco products" Pet. App. 31a. This conclusion followed from the court's analysis of the FDCA and the tobacco-specific statutes. ". . . FDA's need to maneuver around the obstacles created by the operative provisions of the [FDCA] reflects congressional intent not to include tobacco products within the scope of the FDA's authority." *Id.* at 29a-30a. "The fact is that Congress did not equip the FDA with tools appro-

priate for the regulation of tobacco" *Id.* at 30a. "Congressional policy, as set out in the [FCLAA], cannot be harmonized with the FDA's assertion of jurisdiction over tobacco products." *Id.* at 44a. Finally, the court observed: "neither federal agencies nor the courts can substitute their policy judgments for those of Congress." *Id.* at 53a.

Having ruled against FDA on the jurisdictional issue, the court of appeals vacated, and expressly stated no view on, the district court's judgment that the advertising restrictions are unauthorized, *id.* at 54a n.29; and it did not reach any other issue, see *id.* at 1a-54a. FDA's petition for rehearing *en banc* was denied. *Id.* at 137a-46a.

SUMMARY OF ARGUMENT

Prior to its tobacco rulemaking, FDA applied the FDCA's "drug" and "device" provisions only to products whose "intended use," as determined by marketing claims and representations, was to provide "medical" (*i.e.*, health-related) benefits. Accordingly, FDA consistently held that the FDCA does not apply to tobacco products.⁵

In its rulemaking, FDA did not rely on claims or representations by tobacco product manufacturers as establish-

⁵ The general history of FDA's interpretation of the FDCA with respect to tobacco products and of Congress's enactment of tobacco-specific statutes on the basis of its understanding that FDA had no jurisdiction over such products is presented in the Brief of Philip Morris Incorporated and Lorillard Tobacco Company. The Brief of Brown & Williamson Tobacco Corp. presents the history and role of the concept of "intended use" in food and drug law. The Brief of United States Tobacco Co., *et al.* shows that the uses and effects that are relevant under the FDCA's definitions of "drug" and "device" relate to medical or health-related benefits. The Brief of the National Association of Convenience Stores and Acme Retail, Inc. shows that FDA's decision to regulate tobacco products as "devices" preempts or otherwise nullifies a host of State and local enactments relating to tobacco products.

ing an "intended use" to obtain a medical benefit. Instead, FDA departed from the prior settled interpretation of the FDCA's definitions by creating new theories of "intended use," which, if applied consistently, would make unlawful many genuine and medically important drugs and medical devices, and would extend to other products plainly beyond FDA's jurisdiction. FDA's new theories create serious anomalies in other statutes as well.

As the court of appeals held, even if the definitions of "drug" and "device" could be stretched to reach tobacco products, the language and structure of the FDCA as a whole plainly show that Congress did not intend to subject them to the FDCA. FDA's failure to find that tobacco products are effective and safe for any intended use makes it impossible to reconcile their continued marketing as "drugs" and "devices" with the FDCA's requirements that all marketed "drugs" and "devices" be effective and safe. Thus, FDA's assertion of jurisdiction necessarily leads to a ban, a result contrary to congressional intent and unacceptable even to FDA.

Having found tobacco products unsafe, FDA seeks to regulate them without reference to any statutory standard. To avoid both a ban contrary to congressional intent and the constitutional problem resulting from standardless regulation, the Court should interpret the FDCA as not reaching tobacco products.

FDA's assertion of jurisdiction is also irreconcilable with the tobacco-specific statutes. It conflicts with the congressional policy on smoking and health set forth in statutory text, and with the program established by those statutes for the regulation of tobacco products with respect to health and related matters. Moreover, without a clear statement from Congress, and in the teeth of legislation supporting the lead role of the States in controlling underage access to tobacco products, FDA's regulations seize the lead role for FDA.

Ultimately, FDA is left with a plea for *Chevron* deference. Deference is not warranted here. The issue of statutory interpretation relates to multiple statutes, only one of which is administered by FDA; that issue involves policy-making of a kind suitable only for Congress; and FDA has reversed a long-settled interpretation. Moreover, the possibility of *Chevron* deference does not arise until after the Court has concluded that the relevant statutes do not reflect a clear congressional intent; but, here, they do.

In sum, FDA seeks to "cut a great road through the law," *TVA v. Hill*, 437 U.S. 154, 195 (1978) (quoting R. Bolt, *A Man for All Seasons*, Act I (1960)), to seize power over tobacco products. Among the felled trees are long-established principles of food and drug law and statutes designed by Congress to address the concerns raised by tobacco products in a way quite different from FDA's.

ARGUMENT

I. THE TEXT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT IS INCONSISTENT WITH ITS APPLICATION TO TOBACCO PRODUCTS.

The FDCA is one of many statutes that protect the public health, each in a congressionally prescribed domain—*e.g.*, the Consumer Product Safety Act, 15 U.S.C. §§ 2051-84; the Federal Hazardous Substances Act, *id.* §§ 1261-78; the Toxic Substances Control Act, *id.* §§ 2601-92; the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y; the FCLAA; the Comprehensive Smokeless Tobacco Health Education Act, 15 U.S.C. §§ 4401-08; and, with respect to advertising, the Federal Trade Commission Act, *id.* §§ 41-77.

Thus, the FDCA is not, as the Government contends, an essentially limitless "comprehensive, prophylactic statute designed to protect the public health and safety." Pet. Br. 36. Rather, it protects the public health in the respects, to the extent, and in the manner set forth in its

text. *Cf. Director, Office of Workers' Compensation Programs v. Newport News Shipbldg. & Dry Dock Co.*, 514 U.S. 122, 135-36 (1995). It specifies and defines the categories of products it covers: foods, drugs, devices, and cosmetics, 21 U.S.C. § 321(f)-(g)(1) & (h)-(i); and it is designed for regulation of those kinds of products. It is not designed for regulation of tobacco products or other products, which may present health risks in contexts quite different from those of foods, drugs, devices, and cosmetics. As FDA, itself, has recognized, the FDCA does not "provide authority suitable to the regulation of cigarettes." *Novich/Goyan Ltr.* 3 (Jt. App. 50, 54); *see also* *Opp. Cert.* 12 n.9.⁶

An agency may not usurp the role of Congress as the initiator of major change in the regulation of a large sector of the economy, in the allocation of federal administrative jurisdiction, or in the wholesale reorientation of its organic statute. The claim that FDA may dramatically expand the scope and change the operation of the FDCA to do whatever it thinks serves the public interest is ultimately lawless.

[N]o legislation pursues its purposes at all costs. Deciding what competing values will or will not be sacrificed to the achievement of a particular objective is the very essence of legislative choice—and it frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute's primary objective must be the law.

Rodriguez v. United States, 480 U.S. 522, 525-26 (1987) (emphasis in original).

⁶ If, as FDA contends, tobacco products are "drugs" and "devices," then FDA's jurisdiction also reaches tobacco, itself, which is a "component" of such products. *See* 21 U.S.C. § 321(g)(1)(D) & (h). Therefore, FDA's jurisdiction would reach tobacco farms, warehouses, etc., which would be subject to FDA inspection under *id.* § 374.

A. The FDCA's Definitions Do Not Reach Tobacco Products.

Since long before 1938, tobacco products have been thought of as a separate category of products, at the same level of generality as "foods," "drugs," medical "devices," and "cosmetics," and not as a subcategory of any of them. *Opp. Cert.* 2 & n.3. Tobacco products are also different from them with respect to problems presented, public policy, and politics.

Although the terms "drug" and "device" can embrace new products developed after 1938, tobacco products and concerns about their safety were already prominent in the 1930s. *Id.* at 2-3.⁷ The text of the FDCA reflects an understanding that it applies to products marketed for health-related benefits, not to tobacco products. The Government's contrary contention, that the FDCA's definitions "have a scope as broad as their language prescribes," *Pet. Br.* 21, and therefore reach tobacco products, cannot survive analysis.

1. "Intended Use" Is a Term of Art in Food and Drug Law, and Its Claims-Based Meaning Is Necessary to the Proper Operation of the Law.

The definitions of "drug" and "device" apply to "articles (other than food) intended to affect the structure or any function of the body of man or other animals" 21 U.S.C. § 321(g)(1)(C) & (h)(3). The term "intended to affect" was added to food and drug law in 1938. 52 Stat. 1041. It is patterned after "intended for use" in 21 U.S.C. § 321(g)(1)(B) & (h)(2), which derives from section 6 of the 1906 Act, 34 Stat. 769 ("intended

⁷ *See also, e.g., Illinois Cigarette Serv. Co. v. City of Chicago*, 89 F.2d 610, 613 (7th Cir. 1937); *Ploch v. City of St. Louis*, 345 Mo. 1069, 1076-77, 138 S.W.2d 1020, 1023 (1940); *Commonwealth v. McCrary*, 250 Ky. 182, 187, 61 S.W.2d 1043, 1045 (1933); *Ford Hopkins Co. v. Iowa City*, 216 Iowa 1286, 1293-94, 248 N.W. 668, 672 (1933).

to be used"). These terms are referred to together as "intended use." See 21 C.F.R. §§ 201.128, 801.4 (1999).⁸

"Intended use" is a term of art, to which administrative and judicial interpretation has given a special meaning, different from the dictionary definitions of its separate words, and with no origin in the common law.⁹ Congress in 1938 articulated this special meaning:

The use to which the product is *to be* put will determine the category into which it will fall. . . . The manufacturer of the article, through his *representations* in connection with its *sale*, can *determine* the use to which the article is to be put.

S. Rep. No. 361, 74th Cong. 4 (1935) (emphasis added).¹⁰ Courts and, until now, FDA, have treated this passage as authoritative. See *ASH v. Harris*, 655 F.2d 236, 238-39 (D.C. Cir. 1980); *United States v. An Article . . . "Sudden Change,"* 409 F.2d 734, 739 n.3 (2d Cir. 1969); *United States v. 23 . . . Articles*, 192 F.2d 308 (2d Cir. 1951); 56 Fed. Reg. 60,537, 60,546 (1991).¹¹

⁸ All references herein to the C.F.R. are to the 1999 edition.

⁹ Contrary to Pet. Br. 25, "effects" that are intended is not the "decisive factor" in the definitions. The definitions do not use the word "effects." As shown in *Bradley v. United States*, 264 F. 79 (5th Cir. 1920) (water with therapeutic claims is a drug), even a product whose manufacturer knows it has no therapeutic effects can be a drug or device if such effects are claimed.

¹⁰ The phrase "is to be put" (rather than "is put") signifies intended rather than actual use. Contrary to the district court's suggestion, Pet. App. 106a, the Report could not have used "will" rather than "can" in the second quoted sentence because use of "will" would have made the sentence a prediction of future behavior rather than a statement of legal capacity.

¹¹ Intended use, so understood, is analogous to congressional intent, which is not determined from the private thoughts, conversations, or papers of Members of Congress, but only from what is said in certain types of public materials, i.e., statutes, and sometimes legislative history. It is in this sense that longstanding FDA regulations define "intended use" as involving an "objective intent," 21 C.F.R. §§ 201.128, 801.4 (emphasis added), a term unknown to

Thus, a manufacturer can "determine," not merely influence, its product's intended use through "representations in connection with . . . sale." Such representations can determine an intended use that is within the FDCA "drug" and "device" definitions or one that is not. This understanding of "intended use" led FDA to conclude repeatedly that the FDCA does not apply to tobacco products in the absence of therapeutic claims because their customary claims are outside the FDCA's definitions.¹²

ordinary English and the common law. All subjective intent is inferred from objective materials. Therefore, an "objective intent" is not subjective intent, however evidenced. Here, it is the intent communicated in the market by the claims and representations in a product's labeling and advertising. That intent is "objective" in that its locus is not the mind of any person, but the marketing communications, themselves.

Thus, the regulations' requirement of "objective intent" clearly precludes FDA's current theory that an intended use can derive from what manufacturers "have in mind," Pet. Br. 3, e.g., subjective intent, knowledge, or desire. The regulations also make no reference to, and therefore preclude as a basis for "intended use," foreseeability, product design, and actual use for a purpose for which a product is not "offered" (i.e., claimed).

¹² "The statutory basis for the exclusion of tobacco products from FDA's jurisdiction is the fact that tobacco marketed for chewing or smoking without accompanying therapeutic claims, does not meet the definitions in the [FDCA]" Letter from FDA Bureau of Enforcement to Directors of Bureaus, Divisions, and Districts (May 24, 1963), reprinted in 1972 *Hearings* 240. "[FDA] has no jurisdiction under the [FDCA] over tobacco, unless it bears drug claims." 1965 *Hearings* 193. "[C]igarettes recommended for smoking pleasure are beyond the [FDCA]." 1972 *Hearings* 239 (testimony of FDA Comm'r Edwards). "[I]nsofar as rulemaking would relate to cigarettes . . . as customarily marketed, . . . FDA has no jurisdiction." Novitch/Goyan Ltr. 12 (Jt. App. 50, 67). See also 61 Fed. Reg. 45,194, 45,198-99. Thus, contrary to Pet. Br. 42, there was absolutely no "uncertainty . . . about FDA's position."

United States v. 46 Cartons . . . Fairfax Cigarettes, 113 F. Supp. 336 (D.N.J. 1953), and *United States v. 345 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (D.N.J. 1959), do not support the broad proposition that "FDA has previously regulated tobacco products when it has found sufficient evidence that they

Accordingly, FDA has regulated nicotine-containing drugs labeled for smoking cessation, without simultaneously claiming jurisdiction over tobacco products: the former make therapeutic claims; the latter do not.¹³

The theories of "intended use" on which FDA now relies are unprecedented. Until the tobacco rulemaking, neither FDA nor any court had ever held that a foreseeable or widespread consumer use, internal company statements, or a product's design could establish an intended use. Even a manufacturer's undistributed promotional materials with therapeutic claims do not establish an intended use because they have not been *communicated* in the market. *United States v. Articles of Drug for Veterinary Use*, 50 F.3d 497 (8th Cir. 1995). In the present context, foreseeable use, widespread consumer use, and known or desired use are merely ongoing actual use. FDA's theories would substitute "use" for "intended use."

Basing FDA jurisdiction on claims in the market has worked well, and consistently with congressional intent, since 1906. The claims-based understanding has kept FDA jurisdiction within the limits envisioned in 1938 by

were intended to affect the structure or any function of the body," Pet. Br. 24. Rather, they held only that cigarettes bearing therapeutic claims—i.e., uncustomary claims—were drugs. Literally any consumer product is a drug or device subject to the FDCA if marketed with a therapeutic claim. See, e.g., *United States v. 23 . . . Articles*, 192 F.2d 308 (2d Cir. 1951) (phonograph records); *United States v. Undetermined Quantities of Article of Device*, 1982-1985 Developments, Med. Devices Rep. (CCH) ¶ 15,055 (W.D. Mich. Nov. 22, 1982) (tape recordings). FDA has not historically regulated either the recording industry or the tobacco industry.

¹³ The suggestion at Pet. Br. 23 that FDA has jurisdiction over tobacco products *because* it has jurisdiction over nicotine-containing products that make therapeutic claims simply ignores the distinction between the presence and absence of such claims, and FDA's longstanding prior reliance on that distinction, see n.12, *supra*. In addition, the tobacco-specific statutes discussed at pp. 35-44, *infra*, preclude FDA jurisdiction over tobacco products, but not over nicotine-containing non-tobacco products.

Congress and FDA,¹⁴ while enabling FDA to protect the public from any product with an improper health claim.

Claims in the market—oral or written; on labels, in advertising, or in salespersons' presentations—provide an objective, easily identifiable and administrable basis for determining FDA jurisdiction. Virtually no product (especially a new one) can be marketed without some claim(s), express or implied. Even a product name, by itself, may have a secondary meaning that constitutes a claim, e.g., "Prozac." (Tobacco products, of course, are marketed with customary claims.) A product outside FDA's jurisdiction could be regulated by another agency. Thus, a nicotine inhaler marketed for "pleasure," Reply Brief for the Petitioners [in support of Petition for a Writ of Certiorari] 5 ("Pet. Rep."), would be subject to regulation under the Consumer Product Safety Act, and, potentially, the Controlled Substances Act. Street drugs, Pet. Rep. 5, already are regulated under the latter.

FDA's theory that any use that is foreseeable, widespread, known to a manufacturer, or reflected in product design is an intended use is unworkable. In food and drug law, the concept of "intended use" governs two important kinds of determination: (1) whether an approved drug or device needs additional approval for its distribution to be lawful (the issue of "off-label" uses), and (2) whether a product is, indeed, a drug or device (the issue of jurisdiction). See Pet. Br. 27 n.5. FDA's new theories lead to intolerable results in both areas.

Off-Label Uses. In deciding whether a drug or device should be (or remain) approved, FDA is required to assess its effectiveness and safety under the "conditions [of use] prescribed, recommended, or suggested in [its]

¹⁴ See *Foods, Drugs, and Cosmetics: Hearings Before the Senate Comm. on Commerce*, 73d Cong., 518 (1934) (testimony of FDA Chief Campbell).

labeling." 21 U.S.C. §§ 355(d)(1)-(2) & (4)-(5) & (e)(1)-(3), 360c(a)(2)(B), 360e(d)(2)(A)-(B) & (e)(1)(A)-(B). Those conditions are determined by the manufacturer, subject to FDA approval: if FDA finds that a drug or device would be ineffective or unsafe under a particular condition, the product will not be (or remain) approved with that condition. Consequently, FDA approves a drug or device with labeling that specifies particular intended uses (*i.e.*, "indications" for use, which are manufacturer claims), for which FDA has found it effective and safe. *See* 21 U.S.C. §§ 355(b)(1)(F) & (d)(1)-(2) & (4)-(5), 360c(a)(2)(B), 360e(c)(1)(F) & (d)(2); 21 C.F.R. §§ 314.105(b)-(c), 814.44(d)(1). Addition of a new intended use creates a different product. *See*, as to drugs, *id.* § 310.3(h)(4). In general, adequate directions for all intended uses must be in labeling for consumers (non-prescription products) or physicians (prescription products), 21 U.S.C. § 352(f)(1); 21 C.F.R. §§ 201.5(a), 201.100(c)(1), 801.5(a), 801.109(c); Pet. Br. 27 n.5. Any new labeled use must be approved, 21 C.F.R. §§ 314.70(b)(3)(i), 814.39(a)(1)-(2).

However, because Congress intended that FDA not regulate the practice of medicine, physicians may freely prescribe an approved drug or device for unapproved uses (called "off-label" or "unlabeled" uses, because not referred to in the FDA-approved labeling). 37 Fed. Reg. 16,503 (1972); *see also*, *e.g.*, 59 Fed. Reg. 59,820. 59,821 (1994); 44 Fed. Reg. 37,434, 37,435-36 (1979).

[U]nlabeled uses . . . may reflect approaches to drug therapy that have been extensively reported in medical literature. . . . Valid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations. . . . Before such advances can be added to the approved labeling, however, data substantiating the effectiveness of a new use or regimen must be submitted by the manufacturer to FDA for evaluation.

This may take time and, without the initiative of the drug manufacturer whose product is involved, may never occur. For that reason, accepted medical practice often includes drug use that is not reflected in approved drug labeling.

FDA, *Use of Approved Drugs for Unlabeled Indications*, FDA Drug Bulletin, Apr. 1982, at 3. Thus, many drugs (and devices) have medically important off-label uses that are widespread, foreseeable, known to manufacturers, and reflected in their internal papers.

FDA has never treated an off-label use as an intended use where the manufacturer or other vendor did not *claim* the use in connection with sale. If FDA did so, all products with such uses by physicians treating patients or by consumers would be unlawful because they would lack approval, and their labeling would lack adequate directions, for all intended uses.

Basing "intended use" on widespread actual use or otherwise foreseeable use would also make the line between "intended" and not-intended uses uncertain, shifting, and beyond the control of manufacturers. The frequency of particular off-label uses may be difficult to determine, and may fluctuate over time. Consequently, with respect to many off-label uses, manufacturers and FDA would have no reliable means of knowing at any given time whether they are "intended" or not, and thus whether the products being so used are lawful or unlawful.

Therefore, FDA's new theories of "intended use," created to reach tobacco products, cannot be applied consistently without making many medically important drugs and devices unlawful and placing FDA in conflict with Congress's intent that it not regulate medical practice (by deeming unlawful those products that physicians put to off-label use). Theories created "for this day and train only," *Smith v. Allwright*, 321 U.S. 649, 669 (1944) (Roberts, J., dissenting), cannot be sustained.

Jurisdictional Determinations. FDA relies on a literal reading of the FDCA's definitions. Here, however, as in *Lewis v. United States*, 523 U.S. 155, 160 (1998), "a literal reading . . . would dramatically separate the statute from its intended purposes" because the FDCA would apply to a vast array of products that Congress clearly did not intend FDA to regulate. One example is guns. Bullets enter the body; they are commonly used to "affect the structure or . . . function of the body of man or other animals," 21 U.S.C. § 321(h); and their manufacturers design them for, know of, desire, and foresee such uses. Other articles that foreseeably affect bodily functions include thermal clothing, air conditioners, exercise equipment, scuba-diving gear, mattresses, and even roller-coasters and horror movies.

It is no response that FDA could exercise discretion to decline jurisdiction and thereby avoid absurd results. FDA's jurisdiction would then be based not on law, but on agency discretion. But "[t]he determination of the extent of authority given to a delegated agency by Congress is not left for the decision of him in whom authority is vested." *Addison v. Holly Hill Fruit Prods., Inc.*, 322 U.S. 607, 616 (1944).

The *dictum* in *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969), invoked at Pet. Br. 23, is not to the contrary. The Court there held only that "the literal language" of the FDCA's definition of "drug" does not require contact with the body. Here, as shown at pp. 21-35, *infra*, "the literal language" of the FDCA, *taken as a whole*, excludes tobacco products. The Court there relied on the lack of a countervailing congressional direction to exclude an antibiotic sensitivity disk. 394 U.S. at 792. Here, there are congressional directions in the FDCA that unsafe "drugs" and "devices" not be marketed, and in the tobacco-specific statutes that

the health aspects of tobacco products be regulated only under those statutes and under a policy of giving specified warnings while protecting the national economy. Moreover, the *Bacto-Unidisk dictum* does not apply to a situation, like that here, of multiple relevant statutes with countervailing purposes. Finally, FDA, itself, has held that *Bacto-Unidisk* provides no basis for asserting jurisdiction over cigarettes. See Letter from Comm'r Donald Kennedy to John F. Banzhaf, III, at 4 (Dec. 5, 1977) (FDA Dkt. 77P-0185) (Jt. App. 44, 49).¹⁵

2. FDA's Interpretation of "Intended Use" Would Create Anomalies in Other Statutes.

The Consumer Product Safety Act ("CPSA") exempts from the term "consumer product" "drugs" and "devices" "as such terms are defined in . . . the [FDCA]." 15 U.S.C. § 2052(a)(1)(H) (1994). If every consumer product that foreseeably affects the structure or function of the body (or that fits within any of FDA's other new theories of "intended use") is a "drug" or "device," then every such product is excluded from the jurisdiction of the CPSA—whether or not FDA actually regulates it. There are many such products. Indeed, the products the Consumer Product Safety Commission actively regulates are precisely those that foreseeably can affect consumers adversely (*e.g.*, space heaters, electric hair curlers, playground equipment).

¹⁵ The Court in *Bacto-Unidisk* interpreted 21 U.S.C. § 321(g)(1)(B) (the disease-treatment definition of "drug"). FDA here relies on *id.* §§ 321(g)(1)(C) & (h)(3) (the structure-or-function definitions of "drug" and "device"). As to those definitions, FDA "has . . . recognized implicit limitations upon [their] scope." *ASH v. Harris*, 655 F.2d 236, 240 (D.C. Cir. 1980). Moreover, FDA agrees that the other principal provisions of the "drug" and "device" definitions, 21 U.S.C. § 321(g)(1)(A) & (h)(1) (compensial recognition), are not to be read literally. See *National Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325, 337 n.11 (2d Cir. 1977).

The CPSA separately excludes from the definition of "consumer product" "tobacco and tobacco products." *Id.* § 2052(a)(1)(B). Thus, in Congress's dictionary, the terms "tobacco and tobacco products" refer to a class of articles different from "drugs" and "devices" (as defined in the FDCA).¹⁶ FDA's interpretation would make section 2052(a)(1)(B) superfluous. The same problem would arise under the definition of "chemical substance" in the Toxic Substances Control Act, *id.* § 2602(2)(B), and under the definition of "hazardous substance" in the Federal Hazardous Substances Act, *id.* § 1261(f)(2).

The Controlled Substances Act ("CSA") defines "controlled substance" to include all "drugs," as defined in the FDCA, and to exclude "tobacco." 21 U.S.C. § 802(6), (12) (1994). Thus, if tobacco is an FDCA "drug," it is both included in (contrary to expressed congressional intent), and excluded from, the definition of "controlled substance." The same problem would arise under the definition of "consumer commodity" in the Fair Packaging and Labeling Act, 15 U.S.C. § 1459 (1994).

The text of the CSA also contradicts the Government's claim that any product that is taken into the body, has a pharmacological effect, and may be dangerous, has "the classic characteristics of [FDCA] drugs and devices." Pet. Br. 24. The definition of "controlled substance" includes, *in addition to* FDCA "drugs," any "other substance, or immediate precursor, included in" one of the CSA's Schedules. 21 U.S.C. § 802(6). Thus, the CSA demonstrates that the FDCA's definition of "drug" does *not* embrace all substances that are taken into the body and have pharma-

¹⁶ Similarly, the Chairman of the Federal Trade Commission ("FTC"), whose statute includes essentially the same definitions of "food," "drug," "device," and "cosmetic" as the FDCA, compare 21 U.S.C. § 321(f)-(g)(1) & (h)-(i) with 15 U.S.C. § 55(b)-(e), advised Congress in 1964: "A cigarette is not a drug. It is not a food. It is not a device. It is not a cosmetic. It is a thing, a product." 1964 Hearings 125.

cological effects and dangerous abuse potential—the kinds of substances Congress intended to reach in the CSA, *see generally, id.* § 811. Although Congress found that "[m]any" controlled substances have "a useful and legitimate medical purpose," *id.* § 801(1), and therefore are within FDA's jurisdiction, the ones that do not, *e.g.*, hallucinogens, are outside FDA's jurisdiction because they are not marketed with medical claims.

These statutes further demonstrate that Congress distinguishes between FDCA "drugs" (and "devices") and tobacco products. Moreover, these statutes constitute a pattern of congressional decisions to exclude tobacco products from health-and-safety statutes other than the tobacco-specific statutes, and thereby to reserve to Congress, itself, the role of regulatory policy-maker as to tobacco and health.¹⁷

B. The FDCA as a Whole Cannot Apply to Tobacco Products.

The FDCA as a whole precludes application of its definitions of "drug" and "device" to tobacco products, and therefore removes any asserted definitional ambiguity on that point. "Ambiguity is a creature not of definitional possibilities but of statutory context." *Brown v. Gardner*, 513 U.S. 115, 118 (1994). Therefore, "[t]he

¹⁷ The Government infers from the absence of an express exclusion in the FDCA's definitions of "drug" and "device" that Congress intended to leave FDA free to regulate tobacco products as drugs and devices. Pet. Br. 18-19. Because, however, FDA advised Congress in 1964-65 that it had no jurisdiction under the FDCA, *see n.3, supra*, an interpretation it had adhered to for more than 25 years and continued to adhere to for another 30 years, the only reasonable inferences are that it was unnecessary to amend the FDCA to exclude tobacco products, and that Congress intended tobacco products to be regulated, with respect to health, under the tobacco-specific statutes exclusively. FDA so concluded in *Novitch/Goyan Ltr.* 6-7 (Jt. App. 50, 58-59). *See also* authorities cited in *Opp. Cert.* 27, n.24.

plainness or ambiguity of statutory language is determined by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole." *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997). See also, e.g., *United Sav. Ass'n v. Timbers of Inwood Forest Assocs., Ltd.*, 484 U.S. 365, 371 (1988) (provision ambiguous in isolation may be clarified by remainder of statute because only one meaning produces substantive result compatible with the rest of the law).

Accordingly, the FDCA's jurisdictional reach cannot be determined solely by its definitions. Jurisdiction is conferred by imposition of requirements or prohibitions, and by delegation of administrative and enforcement authority. Definitions impose no duties and delegate no power. An interpretation of a definition must yield the kind of results Congress intended when it is implemented by a statute's operative provisions.

Thus, in *Gustafson v. Alloyd Co.*, 513 U.S. 561 (1995), although section 2(10) of the Securities Act of 1933 defined the term "prospectus," the Court determined the scope of that term and the scope of the statute by examining an operative provision: "Although § 10 does not define what a prospectus is, it does instruct us what a prospectus cannot be if the Act is to be interpreted as a symmetrical and coherent regulatory scheme" *Id.* at 569 (emphasis added). See also *Chemehuevi Tribe v. FPC*, 420 U.S. 395, 403-04 (1975) ("[o]ther provisions of the Act make more apparent the limitations intended by Congress upon the reach of [the section relied on]").

This Court frequently has refused to apply a statute's definitions so broadly (even within their literal meaning) as to reach results not intended by the statute's operative provisions. See, e.g., *Reves v. Ernst & Young*, 494 U.S. 56, 63 (1990) ("the phrase 'any note' should not be inter-

preted to mean literally 'any note,' but must be understood against the backdrop of what Congress was attempting to accomplish" (emphasis added); *Norfolk Redevelopment & Hous. Auth. v. Chesapeake & Potomac Tel. Co.*, 464 U.S. 30, 36 (1983) (although C&P literally met statutory definition of "displaced person," Court "must . . . be satisfied that Congress addressed the problem of utility relocation costs in the [statute] before [it] can conclude that C&P is entitled to the benefits it seeks") (emphasis added). See also *Helvering v. Gregory*, 69 F.2d 809, 810 (2d Cir. 1934) (L. Hand, J.) ("[I]t does not follow that Congress meant to cover such a transaction, . . . even though the facts answer the dictionary definitions of each term used in the statutory definition.") (emphasis added), *aff'd*, 293 U.S. 465 (1935).

Here, application of the FDCA to tobacco products would destroy its "coherent regulatory scheme." In the FDCA, Congress did not "address[] the problem" of how to regulate such products; regulation of them was not "what Congress was attempting to accomplish." When the FDCA is viewed as a whole, "it does not follow [from its definitions] that Congress meant to cover" tobacco products, or left the question open to FDA's future determination.

In *MCI Telecommunications Corp. v. AT&T Co.*, 512 U.S. 218 (1994), the Federal Communications Commission ("FCC") had broadly interpreted the term "modify" so as to exempt certain carriers from the statutory requirement to file tariffs. In rejecting the FCC's interpretation, the Court observed that it was "highly unlikely that Congress would leave the determination of whether an industry will be entirely, or even substantially, rate-regulated to agency discretion" *Id.* at 231. It is at least equally unlikely that Congress intended to leave to FDA the determination whether tobacco products will be regulated under the FDCA and even banned.

1. The FDCA Is Designed To Ensure that "Drugs" and "Devices" Are Effective and Safe, But FDA Has Not Found that Tobacco Products Are Effective or Safe.

"A fundamental precept of drug and device regulation in this country is that these products must be proven safe and effective before they can be sold." *More Information for Better Patient Care: Hearing Before the Senate Comm. on Labor and Human Resources*, 104th Cong. 83 (1996) (statement of FDA Dep. Comm'r Schultz). This is the heart of the FDCA.

Contrary to the implication at Pet. Br. 36, 37, the statutory standards for approval are not that a drug or device is "sufficiently effective" and "sufficiently safe." A drug must have been affirmatively "show[n]" to be "effective" and "safe." 21 U.S.C. §§ 355(d)(1)-(2) & (4)-(5). For a device, there must be an affirmative "showing of reasonable assurance that [it] is safe" and "effective." *Id.* §§ 360c(a)(1)(A)(i) & (a)(1)(B), & (a)(1)(C)(i), 360e(d)(2)(A)-(B). These showings must be made on the basis of data from scientific studies. *Id.* §§ 355(b)(1)(A) & (d)(1)-(2) & (4)-(5); 360c(a)(3), 360e(c)(1)(A).

A drug or device is "effective" when, but only when, for those who use it, it provides the health benefits represented in its labeling. *See, e.g., id.* §§ 355(d)(5), 360c(a)(2), 360e(d)(2)(B). A drug or device is "safe" when, but only when, for those who use it, those health benefits outweigh its risks. *See, e.g., United States v. Rutherford*, 442 U.S. 544, 555-56 (1979); *Drug Safety (Part 1): Hearing Before a Subcomm. of the House Comm. on Government Operations*, 88th Cong. 150 (1964) (testimony of FDA Comm'r Larrick). The FDCA provides that

the safety and effectiveness of a device are to be determined—

(A) with respect to the persons for whose use the device is represented or intended,

(B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and

(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

21 U.S.C. § 360c(a)(2)(A)-(C). Thus, for example, an artificial heart may have a substantial risk of failure leading to death, but if it sustains life it may be "safe."

After an extensive review of their health effects, FDA has *not* found that tobacco products are, or that there is "reasonable assurance" that they are, "effective" or "safe," or even that they are "sufficiently effective" or "sufficiently safe." To the contrary, it has found them "unsafe" and "dangerous." *See p. 5, supra.* Under FDA's findings, the risks tobacco products pose are not justified by any affirmative benefits to health.

The attempt at Pet. Br. 32 to analogize tobacco products to toxic anti-cancer drugs fails because the toxicity of such drugs is outweighed by their beneficial effects in treating cancer. FDA has not found that tobacco products provide any medical benefit, *e.g.*, that any person's health would be better if he or she smoked than if he or she did not. Although FDA says that tobacco products are addictive, *i.e.*, that they effectively sustain addiction (viewed by FDA as a disease), it has not found that they are effective or safe in *treating* addiction. Perpetuating an addiction is *not treating* it. A therapeutic substance that would prevent the symptoms of withdrawal from an addicting substance would provide a "benefit to health," but continuing to consume the addicting substance (and in that way avoiding withdrawal symptoms) does not provide a "benefit to health." FDA has not found that tobacco products help a

patient avoid continued addiction to a more harmful substance (as methadone helps avoid continued addiction to heroin). Nor has it found that avoidance of withdrawal symptoms medically justifies continued smoking or makes cigarettes therapeutically "effective" or "safe." Nor has FDA found that tobacco products provide a significant benefit in, or are safe for, tranquilization, stimulation, or weight control. In sum, FDA has not found that any tobacco product provides a benefit to health that justifies its risks for any user.

What FDA has found (for now) is that a tobacco-product ban would have gravely adverse consequences *for society*. For example, FDA refers to burdens on health-care institutions and risks from prospective black market products, 61 Fed. Reg. 44,413; and a black market harms law-enforcement, the economy, and society generally. Considerations of this sort, however, are not a statutorily permitted basis for concluding that a drug or device is, or has a "reasonable assurance" of being, "effective" and "safe." Under section 360c(a)(2)(A)-(C), such conclusions must be drawn "with respect to the persons for whose use the device is represented or intended," "with respect to the conditions of use prescribed, recommended, or suggested in the labeling," and by "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." Given its findings, FDA could not draw such conclusions here, and has not tried to do so.

FDA's weighing of the risks presented by tobacco products against the risks that would be presented by a ban (or its weighing of the risks and benefits of a *ban* rather than those of *tobacco products*, themselves) is not "the mirror image of the analysis approved in *Rutherford*." Pet. Br. 34, but a refusal to perform that analysis. No drug or device has ever been found safe on that basis. The FDCA clearly requires a comparison, on the basis of

scientific data, between the risks and probable benefits of a *drug* or *device* to the *health* of its *users*. FDA would treat section 360c(a)(2)(A)-(C) as satisfied, instead, by hypotheses as to miscellaneous adverse social consequences of the withdrawal of products that provide no benefit to health. FDA's rulemaking made no attempt to justify such a startling new interpretation of this fundamental requirement of the law.

2. The FDCA's Operative Provisions Cannot Accommodate the Ongoing Distribution of Tobacco Products.

To permit the continued distribution of tobacco products under the FDCA, FDA must ignore or distort many of its other important consumer-protection provisions.

1. A drug or device is misbranded and therefore unlawful, 21 U.S.C. § 331(a), if "it is dangerous to health when used in the . . . manner . . . suggested in the labeling thereof." *Id.* § 352(j). FDA has found that "cigarettes and smokeless tobacco are dangerous" 61 Fed. Reg. 44,420; *see also id.* at 44,412, but it never explains why section 352(j) does not apply to these products.¹⁸

2. Before any "new drug" (defined in 21 U.S.C. § 321(p)) is marketed, it must have been approved by FDA as effective and safe. *See* 21 U.S.C. §§ 331(d), 355. Under FDA's theory that tobacco products combine a drug (nicotine) with device "components," a nicotine-containing tobacco product is an unapproved new drug.¹⁹

¹⁸ Indeed, Congress in 1970 directed that cigarettes be labeled as "Dangerous to Your Health," Pub. L. No. 91-222, § 4, 84 Stat. 88 (1970); but Congress did not ban them. Section 352(j) does not allow FDA to consider the factors that led Congress to permit the continued distribution of cigarettes, *see* 15 U.S.C. § 1331(2).

¹⁹ If a tobacco product is a "drug," it is a "new drug" because it is not "generally recognized . . . as safe and effective" within 21 U.S.C. § 321(p).

Its sale, therefore, violates sections 355 and 331(d). FDA simply disregards the settled law that the FDCA prohibits it from allowing the marketing of an unapproved new drug. *See Cutler v. Kennedy*, 475 F. Supp. 838 (D.D.C. 1979); *Hoffmann-LaRoche, Inc. v. Weinberger*, 425 F. Supp. 890 (D.D.C. 1975).

3. A drug or device is misbranded if it fails to bear "adequate directions for use," 21 U.S.C. § 352(f)(1), including, *inter alia*, directions necessary and sufficient to enable a lay person to use the drug or device *safely* for its intended use. *See* 61 Fed. Reg. 44,464; 21 C.F.R. §§ 201.5, 801.5. FDA has found that, even with the current Surgeon General's warnings required by 15 U.S.C. §§ 1333, 4402, tobacco products are unsafe. Thus, in FDA's view, the warnings fail to provide adequate directions for use; and FDA does not propose any different or additional directions (which would be barred by *id.* §§ 1334(a), 4406(a), discussed at pp. 40, 42-43, *infra*). Therefore, it must be FDA's view that adequate directions for use of tobacco products cannot be written.²⁰

4. A drug or device is misbranded if it fails to bear "adequate warnings against use . . . by children." 21 U.S.C. § 352(f)(2).²¹ No exemption is authorized. FDA says its tobacco regulations are needed to prevent a "pediatric disease," resulting from tobacco use by children.

²⁰ Section 352(f)(1) permits FDA to exempt any drug or device from its requirement, but only where other circumstances (*e.g.*, a physician's prescription) reasonably assure its safe use. *See* 21 C.F.R. §§ 201.100-201.129, 801.109-801.127. FDA has never before exempted a drug or device without this assurance. FDA's only asserted justification for exempting tobacco products is that "the way in which these products are used is common knowledge." 61 Fed. Reg. 44,465. Under FDA's findings, however, such knowledge does not reasonably assure *safe* use.

²¹ The warning need not be addressed to children. It may be addressed to adults to prevent use by children, *e.g.*, "Keep out of the reach of children."

61 Fed. Reg. 45,238. Yet, to avoid a conflict between the FDCA and the tobacco-specific statutes, FDA finds that *the current Surgeon General's warnings are "adequate warnings against use . . . by children."* *Id.* at 44,465 (emphasis added). This disingenuous finding, necessary to avoid a ban under section 352(f)(2), is absurd in light of everything else FDA says about tobacco products, including its finding that the current warnings are "not very effective with young people now." 61 Fed. Reg. 44,511.

5. The FDCA requires FDA to classify devices into one of three classes. 21 U.S.C. § 360c(b)(1). Each requires reasonable assurance that a marketed device is effective and safe. *Id.* § 360c(a). FDA's findings require it to put tobacco products in Class III, which covers devices that present "a potential unreasonable risk of illness or injury," *id.* § 360c(a)(1)(C)(ii)(II). Such devices must undergo FDA review before commercial distribution. *Id.* § 360e(a). Here, unless manufacturers could show that there is "reasonable assurance" that their tobacco products are effective and safe, *id.* § 360e(d)(2)(A)-(B), the products would have to be removed from the market, *id.* §§ 331(a), 351(f).

FDA's proposed rule ignored classification; but, in response to comments, FDA said it intends to classify tobacco products at some unspecified time. 61 Fed. Reg. 44,412. FDA thus has shifted from ignoring the statutory mandate to suspending it. Although the FDCA does not set a deadline for classification, where, as here, a supposed device cannot satisfy the requirements applicable to *any* class, indefinite postponement of classification is unlawful. *Heckler v. Chaney*, 470 U.S. 821, 833 (1985) ("Congress did not set agencies free to disregard legislative direction in the statutory scheme that the agency administers.").

6. To protect consumers from unsafe devices, the FDCA provides:

If [FDA] finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the Secretary *shall* issue an order requiring the appropriate person . . . to immediately cease distribution of such device

21 U.S.C. § 360h(e)(1) (emphasis added). Although the finding of "reasonable probability" is discretionary, once FDA makes that finding the statutory text ("shall") mandates a cease-distribution order. All the discretion FDA needs in administering section 360h(e)(1) relates to the making of the predicate finding. Here, FDA has chosen to make that finding. See 61 Fed. Reg. 44,398. To read "shall" here as "may," as FDA now must do to avoid a ban, is contrary to the statutory text, subverts its purpose of protecting consumers, and is unnecessary to its practical administration.²²

In sum, to avoid the ultimate anomaly of a ban, FDA must disregard or distort key consumer-protection provisions of the FDCA. FDA's extremely broad interpretation of the FDCA's definitions (to expand its own jurisdiction) contrasts strikingly with its narrow interpretations or total disregard of the FDCA's operative consumer-protection provisions (which preclude its preferred tobacco regulatory program). FDA has tried to "forc[e] a square peg into a round hole." *Rowland v. California Men's Colony*, 506 U.S. 194, 200 (1993).

²² A cease-distribution order is not, itself, an enforcement action, and so is not a matter of discretion. The order establishes a legal prohibition against further distribution of the product, violation of which may or may not (within FDA's discretion in individual cases) lead to an enforcement action. The order is analogous to an order denying approval of a product.

This transformation of the FDCA is not necessitated by statutory obsolescence. The FDCA is not in need of updating due to congressional neglect or new circumstances. Congress has amended it at least 57 times since 1938, 25 times in the last 19 years. Op. Cert. 19. Most of the circumstances FDA relies on to justify its assertion of jurisdiction became known to the public and Congress during the development of the tobacco-specific statutes from 1964 to 1992.

The point of this analysis is not, as suggested in the dissent below, that, by leaving tobacco products on the market, FDA has failed to exercise its jurisdiction properly. Rather, as the panel majority recognized, the point is that *any* exercise of such jurisdiction, other than a ban, would be contrary to the operative provisions of the FDCA. Since even FDA acknowledges that a ban would be unacceptable, 61 Fed. Reg. 44,413, the only proper conclusion is that the FDCA does not apply to tobacco products. See, e.g., *United States v. X-Citement Video, Inc.*, 513 U.S. 64, 67-69 (1994); *Green v. Bock Laundry Mach. Co.*, 490 U.S. 504, 510-11 (1989).²³

The Government now argues, for the first time, that, if FDA jurisdiction requires a ban, that result should be viewed with equanimity (even though no one supports a ban) because Congress can enact new legislation to

²³ The Attorney General has concluded that FDA lacks authority to permit the continued marketing of an unsafe product. 43 Op. Att'y Gen. No. 19-20 (1979). There, FDA determined that nitrite caused cancer and so was *per se* "unsafe" under 21 U.S.C. § 348 (c)(3)(A) (1976) (since repealed). The Attorney General concluded that, once FDA determined that nitrite was unsafe, it had no authority to permit its continued marketing, even during a limited phase-out. Although the standard of safety for a food additive such as nitrite was different from that for a drug or device, the Attorney General's reasoning also applies to a drug or device found unsafe.

avoid it. Pet. Br. 34-37. This surprising new position should be rejected.

First, it is never a defense for a defective statutory interpretation that Congress can remedy its defects by new legislation.

Second, a ban under the FDCA would be incompatible with "the policy of the Congress," set forth in 15 U.S.C. § 1331, and with the tobacco-specific statutes generally, see pp. 35-44, *infra*. Congress made the political decision in 1965, and has adhered to it ever since, that there is to be no federal ban.

Third, a tobacco ban would be contrary to Congress's intent in enacting the FDCA. In view of the significant place of tobacco products in American life in 1938, widespread concerns about their safety, and the then recent end of alcohol prohibition in 1933, a ban on tobacco products was not reasonably within the contemplation of the enacting Congress. By 1938, we had learned from Prohibition that a ban on a previously lawful product used recreationally for many years by many millions of people is futile and harmful. The 1938 Act's requirements that drugs be shown to be safe and that unsafe drugs and devices not be distributed, 52 Stat. 1051, 1052, precluded any understanding that the FDCA could apply to tobacco products as drugs or devices. *Cf. Sutton v. United Air Lines, Inc.*, 119 S. Ct. 2139, 2147-49 (1999).

Fourth, a ban is, indeed, unacceptable, *even to FDA*. Although the Government's brief now says a ban is tolerable, FDA endorsed and quoted the President's view that a ban "would be wrong." 61 Fed. Reg. 44,419. FDA "strongly" rejected "any claim that the rule is a prelude to or would lead to prohibition," *id.*, and went out of its way to describe some of the harms a ban would cause, *id.* at 44,413. Therefore, FDA's assertion of jurisdiction cannot be upheld on the view, vigorously rejected by FDA

but now advanced *post hoc* by counsel, that a ban is tolerable. *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962).

Finally, petitioners' contention that a ban is acceptable would not save any of FDA's regulations. There is no showing that FDA would have interpreted the FDCA's definitions as it has if it had accepted the conclusion that the outcome of an assertion of jurisdiction, in the absence of new legislation, would be a ban instead of its regulatory program. Therefore, FDA's assertion of jurisdiction cannot be upheld on the theory that a ban is acceptable. *SEC v. Chenery Corp.*, 318 U.S. 180 (1943).²⁴

C. The FDCA Provides No Standard for Ongoing Regulation of Tobacco Products.

FDA has not made the findings of therapeutic effectiveness and safety required by the FDCA to support the distribution of tobacco products as "drugs" and "devices." To the contrary, it has found them "unsafe." See p. 5, *supra*. In nevertheless permitting their continued marketing, FDA has abandoned the FDCA's standards for "drugs" and "devices," and is on its own. A proposed statutory interpretation that would create a standardless delegation should be rejected. *E.g., Industrial Union Dep't, AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 646 (1980) (plurality opinion); *National Cable Television Ass'n v. United States*, 415 U.S. 336, 342 (1974); *see also Mistretta v. United States*, 488 U.S. 361, 373 n.7 (1989). Here, the breach of the constitutional requirement of a statutory standard would be

²⁴ The asserted analogy to saccharin, Pet. Br. 36-37, is inapt. FDA's proposed ban in 1977 was a routine application of the FDCA to an unusually popular product. Saccharin indisputably was within FDA's jurisdiction. It had been the subject of ongoing regulation and prior regulatory actions by FDA for nearly two decades. *See* 24 Fed. Reg. 9368 (1959); 37 Fed. Reg. 2437 (1972); 38 Fed. Reg. 13,733 (1973); 42 Fed. Reg. 1461 (1977).

more egregious than in most other cases that present a delegation problem because FDA does not even contend that Congress has ever made a focused decision to authorize it to regulate tobacco products.

If tobacco products need not be effective and safe, what statutory standard must they meet? What standard provides the "intelligible principle," *J.W. Hampton, Jr. & Co. v. United States*, 276 U.S. 394, 409 (1928), that is necessary (i) to ensure that Congress has made the "important choices of social policy," *Industrial Union Dep't*, 448 U.S. at 685 (Rehnquist, J., concurring), (ii) to direct FDA's exercise of its claimed delegated authority over the regulation of tobacco products, (iii) to provide a basis for judicial review and congressional oversight, and (iv) to guide regulated parties in complying with the statute? FDA has no answer because the FDCA provides no substitute for the standards of effectiveness and safety, no standard at all for ongoing regulation of unsafe drugs and devices.

Moreover, how will FDA know whether or when to ban tobacco products? If the FDCA's standards of effectiveness and safety do not require a ban now, the FDCA provides no standard for weighing all relevant factors (which FDA recognizes include smuggling, black markets, and other matters that go well beyond public health) and deciding whether to ban them in the future. FDA's claimed discretion to ban is standardless discretion.

That FDA seeks to free itself from the requirements Congress put into the FDCA, and has embarked on an exercise of unauthorized political policy-making, is shown by the fact that FDA seeks to regulate tobacco products like no drug or device in the FDCA's history. Despite its findings as to their health effects, FDA's announced program ignores their composition, imposes no performance standards, permits continued (or even expanded) sales to adults without a prescription, and permits the introduction

of new tobacco products. FDA has not applied the FDCA's operative provisions faithfully, but has evaded them, see pp. 24-30, *supra*, so as to gain power to regulate tobacco products while avoiding an immediate ban. FDA has chosen to focus its regulations on their labeling and advertising (long regulated by the FTC²⁵) and their retail display, handling, and sale (long regulated by the States²⁶). FDA says it "believes that adults should continue to have the freedom to choose whether or not they will use tobacco products." 61 Fed. Reg. 44,418. But *Rutherford* held such freedom unavailable under the FDCA as to a drug not shown to be effective and safe. Moreover, even if all its regulations were fully complied with, FDA would still view every tobacco product as ineffective for therapy and unsafe for use by any person at any time (indeed, as ineffective and unsafe for each user as before). That is an absurd outcome of regulation of any "drug" or "device" under the FDCA.

II. WHEN THE FDCA IS READ WITH THE TOBACCO-SPECIFIC STATUTES, IT IS CLEAR THAT IT DOES NOT APPLY TO TOBACCO PRODUCTS.

Any possible ambiguity about whether the FDCA applies to tobacco products is removed by the statutes in

²⁵ See, e.g., 15 U.S.C. § 1333(c); *FTC v. Liggett & Myers Tobacco Co.*, 203 F.2d 955 (2d Cir. 1953), *aff'd on opinion below*, 108 F. Supp. 573 (S.D.N.Y. 1952). The issue whether FDA or the FTC would have authority over the advertising of the products FDA otherwise regulates was highly controversial, and substantially delayed enactment of the original FDCA. The resolution was that all such authority would be delegated to the FTC, and none to FDA. See David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 Law & Contemp. Probs. 2, 13-14, 17, 18-19, 21 (1938). Subsequently, Congress has given FDA only very limited authority over advertising. See 21 U.S.C. §§ 343(a)(2) (vitamins and minerals), 352(n) (prescription drugs), 352(q)(1) (restricted devices), 352(r) (same).

²⁶ See pp. 45-46, *infra*.

which Congress specifically addressed tobacco and health, and did not provide any role for FDA. Where two or more statutes are arguably relevant, “[c]ourts may properly take into account the later Act when asked to extend the reach of the earlier Act’s vague language to the limits which, read literally, the words might permit.” *NLRB v. Drivers, Chauffeurs, Helpers Local 639*, 362 U.S. 274, 291-92 (1960). Here, as to health regulation of tobacco products, the tobacco-specific statutes are not only later and more specific than the FDCA definitions on which FDA exclusively relies, but also reflect the understanding of FDA and Congress that the FDCA does not apply to tobacco products.

United States v. Fausto, 484 U.S. 439 (1988), describes the technique of interpretation most appropriate to the multi-statute aspect of this case: “This classic judicial task of reconciling many laws enacted over time, and getting them to ‘make sense’ in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute.” *Id.* at 453. *See also*, e.g., *International Bhd. of Teamsters v. Daniel*, 439 U.S. 551, 569-70 (1979) (preclusion by later statute of new interpretation of earlier one); *King v. Smith*, 392 U.S. 309, 325-26 (1968).

Although the tobacco-specific statutes do not repeal any part of the FDCA or “preempt” any action by FDA, they do set forth the federal policy and regulatory program that Congress intends shall apply to tobacco and health. Therefore, they preclude any new interpretation of the FDCA that would apply it to tobacco products so as to authorize a different federal policy or program.

A. The Federal Cigarette Labeling and Advertising Act of 1965 Created a “Comprehensive” Program for Regulating Cigarette Labeling and Advertising.

In January 1964, the first Surgeon General’s Report on Smoking and Health raised the question of what the

federal government should do about smoking and health. U.S. Dep’t of HEW, *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service* (1964). HEW Secretary Celebrezze told Congress that jurisdiction under the FDCA “might well” lead to a ban. See n. 4, *supra*. So informed, Congress did not give FDA jurisdiction, but instead enacted the FCLAA, which embodies Congress’s fundamental political choice not to ban cigarettes, and establishes a policy as to smoking and health that sets the boundaries of the federal regulatory role.

It is the policy of the Congress, and the purpose of this chapter, to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby—

(1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and

(2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.

15 U.S.C. § 1331 (Opp. Cert. App. 55a) (emphasis added). As originally enacted in 1965, section 1331(1) read: “the public may be adequately informed that cigarette smoking may be hazardous to health by inclusion of a warning to that effect on each package of cigarettes.” 79 Stat. 282 (Op. Cert. App. 1a).

Clause (B) of subsection (2) states a policy against “diverse, nonuniform, and confusing” labeling and advertising regulations. Contrary to that policy, FDA’s as-

sertion of jurisdiction imposes on tobacco products the FDCA's labeling provisions for drugs and devices generally, 21 U.S.C. § 352, 21 C.F.R. pts. 201, 801, and the labeling and advertising provisions of its tobacco regulations, *id.* §§ 897.24-897.34. These are in addition to the FCLAA's labeling and advertising provisions, which Congress characterized as already "comprehensive."²⁷

Clause (A), which the Government ignores, states a broader policy of protecting commerce and the national economy. This policy is not limited to—or satisfied by—mere avoidance of regulations covered by clause (B). When read together with the other provisions relating to tobacco and health in the FCLAA and the other tobacco-specific statutes, it clearly expresses a congressional intent that there be no ban on national commerce in cigarettes whose labels and advertisements include the warnings prescribed in the FCLAA (*i.e.*, no federal ban).²⁸

²⁷ A contemporaneous definition of "comprehensive" is: "covering completely: inclusive." *Webster's Seventh New Collegiate Dictionary* 170-71 (1965). Congress's characterization of its program as "comprehensive" is not an empirical description. It is a statement of intent, part of a "Declaration of Policy," 15 U.S.C. § 1331.

The reliance on *Banzhaf v. FCC*, 405 F.2d 1082 (D.C. Cir. 1968), at Pet. Br. 45 is misplaced. By its "fairness doctrine" the FCC sought to protect balanced public discourse, not public health. The challenged FCC ruling did not regulate cigarettes or their manufacturing, labeling, or advertising. The court held only that the FCLAA did not preclude the FCC from requiring that broadcasters who air cigarette advertisements also air anti-smoking messages. *Id.* at 1089. That is sharply different from approving FDA's assertion of jurisdiction for the purpose of imposing, not "other types of regulation," but regulation of what the *Banzhaf* court identified as the specific focus of the FCLAA: "cigarette labeling and advertising," *id.*

²⁸ The contention at Pet. Br. 45 that the "FCLAA does not limit the authority of FDA to ban the sale of tobacco products, any more than it limits the authority of a State to do so (as indeed all States have done with respect to sales to minors . . .)" is mistaken. First, a statute stating "the policy of the Congress" clearly binds all federal agencies with respect to all matters within its

B. The Tobacco-Specific Statutes Specify How Congress Intends Tobacco Products To Be Regulated with Respect to Health and Related Matters.

Since 1965, Congress has adjusted and expanded its tobacco-specific program to respond to, *inter alia*, the very concerns FDA says are the bases for its late entry into this field. Today, that program includes the following elements:

Health, Warnings, and Adult Autonomy: Rotating health warnings (four for cigarettes, three for smokeless tobacco) are required on packages and in advertisements; the warning program is administered by the FTC, 15 U.S.C. §§ 1333(c), 4402(a)-(d). Manufacturers must disclose to HHS annual lists of ingredients in tobacco products, and HHS is required to report to Congress on any perceived health effects of the ingredients. *Id.* §§ 1335a, 4403. Federal involvement in smoking-related research, education, and liaison with States and private agencies is coordinated by the Interagency Committee on Smoking and Health, whose designated members do not include FDA. *Id.* § 1341(b).

Advertising: Tobacco product advertising is banned on television, radio, and other electronic media subject to FCC regulation. *Id.* §§ 1335, 4402(f). Permitted advertising is regulated by the FTC. *Id.* §§ 45, 1336.

Addiction: HHS is required to report to Congress on "current research findings . . . on . . . the addictive property of tobacco" and to recommend any needed action. 42 U.S.C. § 290aa-2(b)(2)-(3).

scope. Second, application of the FCLAA to the States is not at issue here. Third, State age-restrictions (which are not bans) are not affected by § 1331 (which is not a clear statement preempting them); those existing in 1965 remained valid, and the compatibility of such restrictions with § 1331 is confirmed by the ADAMHA Amendments, discussed at pp. 43-44, 46, *infra*.

Underage Access: Receipt of full federal substance-abuse block grants by the States is conditioned on their adoption and effective enforcement of a minimum age of 18 to purchase tobacco products. *Id.* § 300x-26.

Reports to Congress. Many provisions require reports to Congress for consideration and possible action.²⁹

The tobacco-specific statutes, in response to diverse interests, state Congress's policy and constitute its program for how and by whom tobacco products are to be regulated. The care Congress has shown in providing in these statutes for health warnings, advertising restrictions, ingredient disclosure to HHS, incentives for States to prevent underage access, and continuing reports to Congress on all aspects of tobacco and health would make no sense if the FDCA applied to tobacco products. These statutes preclude FDA jurisdiction, which clashes with their policy and detailed program in many ways.³⁰

²⁹ HHS reports to Congress periodically on the health effects of smoking, 15 U.S.C. § 1341(a), (c); current information about the health consequences of smoking, *id.* at § 1337(a); smokeless tobacco, *id.* at § 4407; perceived health effects of ingredients added to tobacco in cigarettes, *id.* at § 1335a; and the "addictive property of tobacco," 42 U.S.C. § 290aa-2(b)(2). The FTC reports to Congress annually on cigarette advertising, 15 U.S.C. § 1337(b). The Interagency Committee on Smoking and Health makes biennial reports to Congress on activities to inform the public of smoking risks. *Id.* at § 1341(b), (c). Most of these reports are required to include any recommendations for legislation.

³⁰ The preclusive effect of the tobacco-specific statutes is not limited by 15 U.S.C. §§ 1334, 4406. Nor is our argument based on preemption. Rather, under the cases cited at p. 36, *supra*, we rely on preclusion of a particular statutory interpretation. Moreover, even as to preemption of State action, under *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992), and *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287-89 (1995), the effect of an express preemption provision depends on "the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business,

First, "Congress has clearly enunciated its policy on cigarettes in [section 1331] This act . . . demonstrates that the regulation of cigarettes is to be the domain of Congress." 1972 *Hearings* 242 (testimony of FDA Comm'r Edwards). Congress has specified regulatory requirements and prohibitions in statutory text at a level of detail typical of regulations. It has not delegated to any federal agency (apart from the FTC with respect to the warning program) any regulatory authority over tobacco products in relation to health, advertising, addiction, or underage access. In accordance with its retention of regulatory authority, Congress repeatedly has required agencies to report any new information that might warrant a change in federal tobacco policy, so that Congress can decide what to do. Fairly read, the statutes incorporate the precedent of 1964: when the Surgeon General's Report appeared, HEW did not act unilaterally, but presented recommendations to Congress.

Second, these detailed tobacco-specific statutes specify how and by whom the labeling and advertising of tobacco products are to be regulated with respect to health. The FCLAA is, after all, the "Federal Cigarette *Labeling and Advertising Act*," and section 1331 expressly refers to "a *comprehensive* Federal program to deal with cigarette *labeling and advertising* with respect to . . . smoking and health" (emphasis added). The title of the smokeless

consumers, and the law." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 486 (1996). Thus, preemption of State action beyond the scope of an express provision is permissible. See, e.g., *Boggs v. Boggs*, 520 U.S. 833 (1997). A similar analysis applies to preclusion of federal agency action. Here, the FCLAA's preclusive effect on federal agencies should effectuate the policy stated in § 1331, with which FDA jurisdiction is incompatible. Finally, the special sensitivity as to implied *preemption* reflected in *Cipollone* derives from the constitutionally-protected role of the States in the federal system. *Medtronic*, 518 U.S. at 485. No such sensitivity applies to statutory *preclusion* of an assertion of authority by a federal agency.

tobacco act—Comprehensive Smokeless Tobacco Health Education Act of 1986 (“CSTHEA”), Pub. L. No. 99-252, 100 Stat. 30 (1986)—expresses congressional intent that it be treated as “comprehensive” with respect to the matters it addresses. Only the FTC and the Justice Department (“DOJ”) may administer and enforce these statutes. *See* 15 U.S.C. §§ 1333(c), 4404, 4405 (FTC jurisdiction), 1338-39, 4404(a)(2), 4405 (DOJ enforcement authority). Yet, FDA’s claim of jurisdiction would make *it* the lead agency in regulating tobacco product labeling and advertising.

Third, Congress’s policy of protecting the national economy while informing consumers of the risks from tobacco use, 15 U.S.C. § 1331, is incompatible with the application of the FDCA to tobacco products. In the regulation of drugs and devices, FDA is not permitted even to consider “commerce and the national economy,” and so cannot implement the congressional policy stated, and the complex balance of interests reflected, in section 1331(2). Thus, in regulating cigarettes, FDA must disregard the very policy Congress declared for health-regulation of cigarettes. *Cf. United States v. Hutcheson*, 312 U.S. 219, 233-36 (1941) (policy statement in labor statute precludes proposed interpretation of antitrust statute as applied to union conduct).

Fourth, FDA’s claim of jurisdiction also clashes with 15 U.S.C. §§ 1334(a), 4406(a). Even FDA agrees that they bar it from requiring on tobacco product packages any “statement relating to [smoking or use of smokeless tobacco products] and health” other than the ones prescribed by Congress. 61 Fed. Reg. 44,544-45. Yet, regulation of product labels to protect health is critical to the FDCA. *See* 21 U.S.C. § 352; 21 C.F.R. pts. 201, 801. If the FDCA applies to tobacco products, it is

anomalous that FDA cannot exercise as to them that core authority.³¹

Fifth, FDA’s designation of tobacco products as “drugs” and “devices” would also make irrelevant 15 U.S.C. §§ 1335a, 4403, which specify procedures and confidentiality for carefully limited disclosures to HHS of information about ingredients in tobacco products. Under the FDCA, much broader disclosures of ingredients would be required, including disclosures to the public, without the special protections in sections 1335a and 4403. *See* 21 U.S.C. §§ 352(e)(1)(A)(ii)-(iii), 355(b)(1)(B)-(C), 360(k), 360e(c)(1)(B); 21 C.F.R. §§ 314.50(d)(1)(ii)(a), 807.92(a)(4), 814.20(b)(4)(ii). FDA could also obtain ingredient information by inspections under 21 U.S.C. § 374(a)(1).

Sixth, FDA’s approach to reducing underage use of tobacco products disregards the limits Congress observed in 42 U.S.C. § 300x-26 (the “ADAMHA Amendments”).

³¹ To avoid §§ 1334(a) and 4406(a), FDA contends disingenuously that the statement it would require on tobacco products (“Nicotine-Delivery Device for Persons 18 or Older”), 21 C.F.R. § 897.25, does not relate to tobacco and health. *See* 61 Fed. Reg. 44,544. Yet, protecting minors from nicotine addiction is the asserted basis for all of FDA’s tobacco regulations. *See id.* at 44,399. The manifest purpose of the statement is to convey to consumers that tobacco products deliver what FDA has found to be an addictive drug, and to warn against what FDA calls a “pediatric disease,” *id.* at 45,238. Because FDA does not administer the FCLAA or the CSTHEA, its interpretation of those statutes is not entitled to deference. *See Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649-50 (1990).

The district court erred in holding that FDA’s statement is not the type of “cautionary statement[]” required by § 1333 and covered by § 1334(a) because it “merely provides basic information to those coming into contact with the product.” Pet. App. 95a-97a. FDA’s statement is indistinguishable in character from the “SURGEON GENERAL’S WARNING: Cigarette Smoke Contains Carbon Monoxide,” 15 U.S.C. § 1333(a). Both provide factual information relating to a risk.

That statute focuses on restricting sales to minors, whereas FDA also imposes restrictions on advertising—a type of regulation that raises troubling issues of public policy and constitutionality, and that Congress addressed differently in 15 U.S.C. §§ 1335, 4402(f). (Additional conflicts between FDA jurisdiction and the ADAMHA Amendments are discussed at pp. 46-47, *infra*.)

In sum, when all the relevant statutes are read together, the only way they can all make sense is for the FDCA not to cover tobacco products. The tobacco-specific statutes do not merely “address narrow issues,” Pet. Br. 16. They are “the later statute[s], the more specific” and “represent[] Congress’ detailed judgment,” *United States v. Estate of Romani*, 523 U.S. 517, 532 (1998), as to how the federal government shall address tobacco and health. “Absent a text that clearly requires it, [the Court] ought not expand . . . one piece of the regulatory puzzle so dramatically as to make many other pieces misfits.” *United States v. Sun-Diamond Growers*, 119 S. Ct. 1402, 1410 (1999).

III. THE CLEAR STATEMENT RULE PROTECTING THE ROLE OF THE STATES IN THE FEDERAL SYSTEM PRECLUDES APPLICATION OF THE FDCA TO TOBACCO PRODUCTS.

“[I]t is incumbent upon the federal courts to be certain of Congress’ intent before finding that federal law overrides” “the usual constitutional balance of federal and state powers.” *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991) (quoting *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 243 (1985)). See also, e.g., *BFP v. Resolution Trust Corp.*, 511 U.S. 531, 544 (1994).

Here, without a clear authorizing statement by Congress, FDA would upset that balance with respect to regulation of local retail display, handling, and sale of tobacco products. FDA jurisdiction would unavoidably (i) inject federal regulation into an area of local activity

historically regulated by the States exclusively, (ii) preempt contrary State approaches unless FDA, in its discretion, grants waivers, and (iii) create potentially massive new federal penal jurisdiction over improper local sales of tobacco products.

Regulating tobacco retailers and restricting underage access to tobacco products are traditional State functions.

For a number of years there has been a well-settled opinion that the use of cigarettes especially by persons of immature years was harmful, and the courts have recognized that they were deleterious in their effects. Their sale and use have been regulated and prohibited by legislative bodies, and these measures have been upheld as a proper exercise of the police power.

State v. Nossaman, 107 Kan. 715, 717, 193 P. 347, 348 (1920). See also, e.g., *Gundling v. City of Chicago*, 177 U.S. 183 (1900) (licensure of cigarette retailers); *Illinois Cigarette Serv. Co. v. City of Chicago*, 89 F.2d 610 (7th Cir. 1937) (ban on cigarette vending machines; ordinance also banned sales to minors and sales within 300 feet of schools); *Bernstein v. City of Marshalltown*, 215 Iowa 1168, 248 N.W. 26 (1933) (permit to sell cigarettes); *Nash-Finch Co. v. Beal*, 124 Neb. 835, 248 N.W. 374 (1933) (licensure system to enforce ban on sale of cigarettes to minors); *Macke v. Commonwealth*, 156 Va. 1015, 159 S.E. 148 (1931) (licensure of tobacco retailers; ban on cigarette vending machines); *Brennan v. City of Seattle*, 151 Wash. 665, 276 P. 886 (1929) (ban on cigarette vending machines); *State v. Olson*, 26 N.D. 304, 144 N.W. 661 (1913) (ban on snuff); authorities cited at Opp. Cert. 3.³² Every State prohibits the sale of to-

³² Without considering the relevant historical evidence, FDA flatly denied “that regulation of tobacco sales or decisions about eligibility and maturity are traditional State functions.” 61 Fed. Reg. 44,429.

bacco products to persons below age 18.³³ FDA's regulations would intrude into this zone, *see* 21 C.F.R. §§ 897.14, 897.16(c), and wrest the lead policy-making and enforcement role from the States.

Moreover, under 21 U.S.C. § 360k(a), all State laws that address the retail display, handling, or sale of tobacco products, and that differ from FDA's tobacco regulations, would be preempted.³⁴ An intent to preempt a traditional police power of the States must be "clear and manifest." *E.g., Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 146 (1963); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Although such an intent is expressed in section 360k as to genuine devices, it is absent as to tobacco products; and, indeed, the ADAMHA Amendments clearly express an intent *not* to preempt. The strategy of the Amendments is twofold: (1) the initiative for restricting underage access to tobacco remains with the States, exercising their traditional police power, and (2) financial incentives are provided to the States to increase the effectiveness of their restrictions. The limited federal role leaves maximum flexibility to the States. *See* 61 Fed. Reg. 1492, 1495 (1996) (preamble to HHS's implementing regulations).

FDA's uniform national program to deal with underage access, however, would divest the States of the very flexi-

³³ The Substance Abuse and Mental Health Services Administration ("SAMHSA") recently reported to Congress that "[a]ll States are in material compliance with the [ADAMHA Amendments]. They have laws prohibiting the sale or distribution of tobacco to minors, and they are enforcing those laws. . . . All States expect to achieve the goal of a maximum sales-to-minors rate of 20 percent by Federal Fiscal Year (FFY) 2003." SAMHSA, *Synar Regulation Implementation FY 97 State Compliance 1* (undated).

³⁴ On petition by a State, FDA may, in its discretion, waive preemption. 21 U.S.C. § 360k(b). The preemptive language of § 360k applies to FDA's tobacco regulations only because FDA has chosen to regulate tobacco products as devices. There is no counterpart to § 360k as to drugs.

bility Congress intended to preserve. It would substitute federal for State initiative: the States would merely implement FDA's program (under contracts with FDA) rather than initiate and implement their own programs. To take any additional steps different from FDA's, they would need FDA's permission.

Finally, under FDA's regulations, every improper sale or failure to verify a purchaser's age in a local convenience store or gas station would be a federal offense, 21 C.F.R. § 897.1(b); 21 U.S.C. § 331(b) & (k), punishable by federal prosecution, *id.*, § 333(a)(1), or by civil penalty imposed by FDA and reviewable in the federal courts of appeals, *id.* § 333(f).³⁵ But "Congress has traditionally been reluctant to define as a federal crime conduct readily denounced as criminal by the States. . . . [W]e will not be quick to assume that Congress has meant to effect a significant change in the sensitive relation between federal and state criminal jurisdiction." *United States v. Bass*, 404 U.S. 336, 349-50 (1971) (rejecting, in absence of clear statement of congressional intent, "the broad construction urged by the Government [, which] renders traditionally local criminal conduct a matter for federal enforcement"). That some State Attorneys General welcome this transfer of responsibility from themselves to FDA does not make it consistent with congressional intent.

IV. FDA'S ASSERTION OF JURISDICTION IS NOT ENTITLED TO DEFERENCE.

The Government's last refuge is a plea for deference under *Chevron U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984). No such deference is warranted. Congress's intent is clear: tobacco products are to be regulated under

³⁵ Such violations also could lead to federal court proceedings for seizure of affected products under 21 U.S.C. § 334, and for injunctions under *id.* § 332.

the tobacco-specific statutes, not the FDCA. Moreover, this case deviates from *Chevron* in critical respects.

The issue of statutory interpretation here involves multiple statutes. Only the FDCA is administered by FDA. The tobacco-specific statutes are not, they are more recent, and they address the specific subject at hand. As to them, FDA has no delegated interpretive authority. See *Adams Fruit*, 494 U.S. at 649-50.

The issue does not involve routine interpretation in a field previously regulated. FDA seeks not to fill a gap, but to annex a continent. It is not "defining a term in a way that is reasonable in light of the legislature's revealed design," *NationsBank, N.A. v. Variable Annuity Life Ins. Co.*, 513 U.S. 251, 257 (1995), but is disregarding Congress's revealed design for regulation of tobacco products and health. As FDA has acknowledged, "the regulation of cigarettes raises societal issues of great complexity and magnitude. It is vital in this context that Congress provide clear direction to the agency." Letter from Comm'r David A. Kessler to Scott Ballin, Esq., 3 (Feb. 25, 1994), reprinted in *Regulation of Tobacco Products (Part 1): Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 103d Cong. 25, 27 (1994). Despite Congress's decisions in enacting the tobacco-specific statutes, FDA seeks to decide anew *by whom* and *how* tobacco products shall be regulated, and *whether* they may continue to be sold at all. As the court below observed, "this type of decision involving countervailing national policy concerns is just the type of decision for Congress." Pet. App. 22a. Congress did not consider these concerns or make this type of decision as to tobacco products in 1938, and FDA is not entitled to deference to an agency decision masquerading as one by the 1938 Congress. See generally, e.g., *BATF v. FLRA*, 464 U.S. 89, 97 (1983) (no deference to agency's "unauthorized assumption . . . of major

policy decisions properly made by Congress"); *United States v. Haggard Apparel Co.*, 119 S. Ct. 1392, 1400 (1999) (Congress makes "general policy," agency implements it); Stephen Breyer, *Judicial Review of Questions of Law and Policy*, 38 Admin. L. Rev. 363, 370-71 (1986) (unlikely that Congress would leave question of great importance and delicacy to agency to decide).

Contrary to Pet. Br. 16, FDA is not entitled to deference on the theory that the question presented is whether the FDCA, which it administers, applies to a particular category of products. The possibility of *Chevron* deference would not arise until *after* the Court at step 1 had determined whether the FDCA or any other statute clearly answers that question. The Government's approach would simply dispense with step 1.

Finally, although "the mere fact that an agency interpretation contradicts a prior agency position is not fatal," *Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. 735, 742 (1996), here FDA's new interpretation is contrary to its contemporaneous interpretation, which, for more than half a century, FDA consistently adhered to in administering the FDCA and presented to Congress as critical background to further legislation. That original interpretation has also been upheld by the courts.³⁶ Consequently, even if *Chevron* applied, FDA's current interpretation should receive little, if any, deference. *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 417 (1993); see also *Department of Commerce v. United States House of Representatives*, 119 S. Ct. 765, 778 (1999).

The Court, therefore, should address the issue presented outside the *Chevron* framework, and adopt "the better reading of the statute[s] under ordinary principles of con-

³⁶ See *ASH v. Harris*, *supra*; *FTC v. Liggett & Myers Tobacco Co.*, *supra* (interpreting language in Federal Trade Commission Act identical to that in FDCA).

struction." *California Dental Ass'n v. FTC*, 119 S. Ct. 1604, 1610 (1999). Even if *Chevron* applied, however, we have shown that the reading of the FDCA as not reaching tobacco products is not merely the "better" one, but also the one required by Congress's clear intent in both the FDCA and the tobacco-specific statutes.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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Petitioners,
v.

BROWN & WILLIAMSON TOBACCO CORPORATION, *et al.*,
Respondents.

On Writ of Certiorari to the
United States Court of Appeals
for the Fourth Circuit

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QUESTION PRESENTED

The ultimate issue in this case is whether Congress delegated to the Food and Drug Administration ("FDA"), through the Federal Food, Drug, and Cosmetic Act ("FDCA"), the authority to regulate tobacco products as drugs and devices. To sustain its claim to such authority, FDA must establish, *inter alia*, that tobacco products are "articles . . . intended to affect the structure or any function of the body of man" within 21 U.S.C. § 321(g)(1)(C) (drug definition) and 21 U.S.C. § 321(h)(3) (device definition). The specific question addressed in this brief is:

Whether FDA's findings that tobacco products have physical effects on the body when used by consumers in ways that manufacturers foresee and desire, are legally sufficient to establish that these effects are "intended" within the meaning of the FDCA's definitions of "drug" and "device" when:

- a) FDA did not find that the manufacturers of tobacco products claim those effects in selling or offering to sell their products;
- b) The proper operation of the FDCA requires that manufacturers have the ability to determine, through their claims, the "intended uses" of their products; and
- c) For almost a century, as Congress shaped the FDCA, FDA repeatedly and consistently stated to Congress, the courts, and the public, that manufacturer claims are determinative of "intended use," and the courts uniformly implemented FDA's interpretation.

Questions presented by the briefs of other respondents include whether the "effects" found by FDA are cognizable

under the FDCA, even if they are claimed, and whether FDCA authority extends to tobacco products as a class, even though Congress did not provide FDA with tools suitable for regulating tobacco, and instead established a separate comprehensive program to regulate smoking and health which is inconsistent with FDA jurisdiction under the FDCA. Brown & Williamson Tobacco Corporation ("Brown & Williamson") agrees that this case also presents those questions, and it concurs in the presentation thereof by the other respondents.

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IN THE
Supreme Court of the United States

No. 98-1152

FOOD AND DRUG ADMINISTRATION, *et al.*,
v. *Petitioners,*

BROWN & WILLIAMSON TOBACCO CORPORATION, *et al.*,
Respondents.

On Writ of Certiorari to the
United States Court of Appeals
for the Fourth Circuit

BRIEF OF RESPONDENT
BROWN & WILLIAMSON TOBACCO CORPORATION

STATUTORY PROVISIONS INVOLVED

This brief deals with the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 321 *et seq.*¹ as it has been amended from time to time, and its predecessor, the Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906) ("Pure Food and Drugs Act").²

STATEMENT OF THE CASE

To bring tobacco products within its authority under the FDCA as "drugs" or "devices," FDA must establish that these products are "intended to affect the structure

¹ Reprinted in United States Tobacco Company, *et al.*, Appendix, at 1a-11a.

² Reprinted in *id.* at 12a-51a.

or any function of the body of man." 21 U.S.C. §§ 321 (g)(1)(C), 321(h)(3). If tobacco products are not so "intended," they do not meet the FDCA's jurisdictional standard, FDA's assertion of jurisdiction must be set aside, and FDA's tobacco regulations, *see* 61 Fed. Reg. 44,396 (1996), must be declared void.³

A. FDA's New Theory Of "Intended Use."

In comments filed in the FDA rulemaking, Brown & Williamson and other manufacturers of tobacco products demonstrated that "intended use" is a term of art under the FDCA, and that it refers to "claims made by the manufacturer in marketing the product."⁴ *See* Brown & Williamson Tobacco Corp. *et al.*, "Comments On Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products," at II-1. (FDA Docket Nos. 95N-0253, 95N-0253J) (1995) ("*Industry Comments*").⁵ The *Industry Comments* argued that FDA's new position, under which manufacturer claims no longer are determinative, "would convert every foreseeable off-label use of a drug or device into an intended use attributable to the manufacturer." *Id.* at II-40. As a result, the "FDCA would be unworkable," and the accepted and important use of approved drugs for unlabeled uses—commonly called "off-label uses"—would be undermined. *Id.* at II-40-41.

FDA did not respond to these arguments. It did not discuss how the FDCA would function if unclaimed but

³ The brief of United States Tobacco Company, *et al.*, demonstrates that FDA also must show that "intended uses" are medical in nature. That is a separate issue from the meaning of "intended."

⁴ In some circumstances, the FDCA treats other vendors, *e.g.*, distributors, importers, or retailers, in the same manner that it treats manufacturers. Brown & Williamson uses the term "manufacturer" to mean all relevant vendors.

⁵ Copies of Volume II of the *Industry Comments*—discussing the meaning of "intended use"—are lodged with the Clerk of the Court.

foreseeable uses were "intended uses," nor did it explain how its new theory would affect the off-label uses of approved drugs that are central to many fields of medical practice. FDA was clear, however, that its claim to jurisdiction over tobacco products was not based on manufacturer claims, but rather on foreseeable and subjectively desired consumer uses.⁶

FDA made extensive findings concerning the bodily effects of nicotine. *See* 61 Fed. Reg. 44,619, 44,739-44, 44,811-23 (1996). It found that consumers use tobacco products to achieve four allegedly jurisdictional effects: sustenance of addiction, weight loss, sedation, and mental stimulation. *See id.* at 44,665-66, 44,811-23. It further found, from various sources including product design and internal company documents, that manufacturers foresee these unclaimed effects, and subjectively desire that con-

⁶ The FDA Brief incorrectly claims that "FDA also relied upon evidence that tobacco manufacturers advertise that tobacco products will provide 'satisfaction,'" and that "'satisfaction' [is] a code word for the pharmacological effects of nicotine." FDA Br. at 7-8 n.2. In fact, FDA's statement justifying the rule explicitly *rejected* a claims-based theory of jurisdiction:

In concluding that these products [cigarettes and smokeless tobacco] are drug delivery devices within the meaning of the Act, the Agency is relying not on product labeling or express representations in promotional materials, but on other relevant objective evidence of intended use.

61 Fed. Reg. 44,619, 45,194 (1996) (footnote omitted) (emphasis added); *see also id.* at 45,198-99. Consistent with this statement, FDA did not identify any brands that currently make "satisfaction" claims. Moreover, a claims-based rationale would apply only to the brands bearing a given claim, and could not justify a categorical rule. Furthermore, FDA did not cite a contemporary study of the meaning of "satisfaction" or other tobacco product claims to consumers. Therefore, contrary to the FDA Brief, FDA's assertion of jurisdiction must, in the first instance, stand based on FDA's theory that the "intended use" of tobacco products is determined by consumer uses that the manufacturer foresees and subjectively desires, and not by manufacturer claims. *See SEC v. Chenery Corp.*, 318 U.S. 80, 94 (1943).

sumers experience them. *See id.* at 44,854-915, 44,986-92. FDA asserted that the four so-called "drug-like" uses are "predominant" or even "nearly exclusive," but it did not quantify those terms. FDA acknowledged that there are "non-drug" uses of tobacco products, but asserted that those uses are "secondary."⁷

To conclude that its findings were legally sufficient to establish that "drug-like" effects are "intended" notwithstanding the absence of manufacturer claims, FDA relied on three propositions, the first two of which explicitly rest on subjective intent. First, FDA said that "persons can be held to 'intend' the reasonably foreseeable consequences of their actions." *Id.* at 44,691. Thus, all foreseeable uses are "intended." *Id.* at 44,692. Second, FDA cited a dictionary to show that "intended" use is what "manufacturers 'have in mind.'" *Id.* at 44,637. It said standardized nicotine levels and internal manufacturer docu-

⁷ FDA's initial jurisdictional analysis accompanying the Proposed Rule said that 75% to 90% of "frequent smokers" are dependent on nicotine. 60 Fed. Reg. 41,453, 41,465 (1995). Obviously, the percentage may be considerably lower for all smokers. In its final Jurisdictional Determination, FDA abandoned the word "frequent" and stated instead that its use of the term "smokers" would reflect the definitions used in the particular study being discussed. 61 Fed. Reg. at 44,730 n.122. Because FDA's final determination that "75% to 90% of smokers" are nicotine dependent rests on multiple studies of differing populations and appears to use the same figure initially attributed only to frequent smokers, what its finding means is unclear. Moreover, FDA found that a group of "young smokers" (those with a median age of 26) had a dependency rate of 51%, and that lower rates are associated with younger age. *Id.* at 44,834. FDA did not discuss the extent, if any, to which tobacco products are used for "drug-like" purposes by non-dependent smokers. FDA agreed that consumers "perceive" themselves to use tobacco for "nonpharmacological" persons such as "taste" or "the ritual" of smoking. *Id.* at 44,823-24. It claimed, however, that these uses are "secondary" to pharmacological effects. *Id.* at 44,824. FDA did not discuss whether the reasons that individuals start smoking are "pharmacological," nor did it explain why it declined to consider such reasons in its analysis of smokers' dependency on nicotine.

ments show that manufacturers "have in mind" "drug-like" uses. *Id.* at 44,637, 44,642.

Third, FDA stated, "Where consumers use a product predominantly or nearly exclusively to obtain any of the [bodily] effects . . . such evidence . . . alone [is] sufficient to establish manufacturer intent." *Id.* at 44,807. FDA did not derive this proposition of law from the language of the FDCA, nor did it explain how consumer use could establish a manufacturer's objective intent, as opposed to a subjective expectation or desire. Instead, it relied on dictum which suggested that FDA could infer "intended use" from evidence (i) that a product is used "almost exclusively for therapeutic purposes," and (ii) that it "lack[s] . . . recognized [nondrug] use." *National Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325, 334 (2d Cir. 1977). Finally, FDA asserted that each of the three principles "independently support[ed]" its assertions about "intended use," and that the "cumulative effect" of the principles was conclusive. 61 Fed. Reg. at 45,204.

B. The Lower Courts' Treatment Of FDA's Theory Of "Intended Use."

The district court accepted FDA's theory. *See* Appendix to Petition for Writ of Certiorari, at 102a-120a ("FDA App."). The court of appeals reversed and rejected FDA's "mechanical reading of only the definitions provisions," observing that:

As noted by the district court, "*no court has ever found that a product is 'intended for use' or 'intended to affect' within the meaning of the [Act] absent manufacturer claims as to that product's use.*" Even the FDA does not contend that tobacco manufacturers make any such claims.

FDA App. at 19a (citation omitted).⁸ On broader grounds, the court of appeals held that tobacco products

⁸ All emphasis herein is added unless otherwise stated.

simply do not "fit into the overall regulatory scheme created by Congress." *Id.* at 20a.

SUMMARY OF ARGUMENT

Since 1906, "intended use" has been a central concept and term of art in federal food and drug regulation. It first was used to refer to what manufacturers communicated through their drug labels, and was later broadened to include manufacturer claims objectively made in "labeling." As Congress shaped the FDCA, FDA repeatedly advised that "intended uses" were determined by manufacturer claims. Courts followed FDA's view, and Congress acted in light of this settled understanding. The critical test was the objective intent expressed in promotional claims; subjective intent was irrelevant.

In crafting the term of art "intended use" over the years, Congress accommodated two objectives: subjecting promotional claims to FDA regulation, including premarket review, and preserving the freedom of medical professionals to practice in accordance with their professional judgment. Congress provided that, if a manufacturer wishes to make a promotional claim to a potential customer, it must first prove to FDA that the claimed use is safe and effective. However, Congress imposed no such duty on a manufacturer for uses the manufacturer does not promote. Nor did Congress empower FDA to regulate unpromoted off-label uses of lawfully sold products. Instead, such uses were left to control by professional medical standards.

FDA's assertion of jurisdiction over tobacco products is inconsistent with the congressionally-enacted meaning of "intended use." FDA now argues that manufacturer claims are not determinative, and that any foreseen, desired, or nearly exclusive use is an "intended use." FDA's new position would prevent the FDCA from working as Congress drafted it, delay the introduction of pioneer drugs, stymie generic competition, interfere with the free-

dom of the medical profession to develop and prescribe beneficial off-label uses, and thus disrupt the harmonious working of the FDCA. FDA's effort to regulate tobacco products by evading the limitations that Congress incorporated into "intended use" is unlawful and must be set aside.

ARGUMENT

I. BEGINNING WITH THE 1906 ACT, MANUFACTURER CLAIMS DETERMINED A PRODUCT'S "INTENDED USE" AND, HENCE, ITS REGULATORY STATUS.

FDA's assertion of jurisdiction over tobacco products rests on its newly-created theory that a manufacturer's subjective intent, not communicated in promotional claims, can establish a product's "intended use." "Intended use" is a term of art that permeates food and drug law.⁹ It appears in twenty-seven sections of the FDCA and in over 900 sections of the FDCA's implementing regulations.¹⁰

The "intended use" concept originated in the Pure Food and Drugs Act of 1906, which focused on manufacturer statements on the product label. Over the decades, that meaning became tightly woven into the fabric of the FDCA. Its lengthy history and its role in the structure and established operation of the FDCA make clear that an "intended use" is one that a manufacturer communi-

⁹ Where Congress relies on a term of art, an agency may not ignore that term of art and supply its own meaning. *See Glaxo Ops. UK Ltd. v. Quigg*, 894 F.2d 392, 397 (Fed. Cir. 1990) (rejecting FDA's interpretation of "active ingredient" where the term was "well-known and well-defined at the time the Act was passed"); *Theiss v. Witt*, 100 F.3d 915, 918 (Fed. Cir. 1996) (*en banc*) (prohibiting agency from creating its own definition of legislative term of art); *Mississippi Poultry Ass'n v. Madigan*, 9 F.3d 1113, 1114 (1993), *aff'd on reh'g*, 31 F.3d 293 (5th Cir. 1994) (same).

¹⁰ These figures are based on a search of the FDCA and its regulations on West PREMISE 3.7 CD-ROM (updated June 1, 1999) using the query "intend! w/4 use."

cates to potential consumers of its products. A manufacturer's subjective desire or expectation which is not objectively present in promotional claims does not establish an "intended use." To the contrary, as the FDA Brief concedes, the words "'intended use' (or words to that effect) refer to 'the *objective* intent of the persons legally responsible.'" FDA Br. at 26 (quoting 21 C.F.R. §§ 201.128 (drug), 801.4 (device)). Thus, unclaimed uses—so-called "off-label" uses—are common and important, but they are *not* "intended uses," and they do *not* trigger FDA jurisdiction, even though manufacturers may foresee and subjectively desire them.

A. The Pure Food and Drugs Act of 1906.

The Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768, represented Congress' first enactment of national legislation to protect consumers in their capacity as vulnerable purchasers of medical products. Section 6 of the Act defined "drug" as "all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, *and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals.*" *Id.* at 769. The dual definition encompassed both "medicines and preparations" recognized in one of the designated compendia and "any substance or mixture of substances" that was "intended to be used" to fight "disease."

The Act was "aimed at cheats." H.R. Rep. No. 59-2118, at 7 (1906). As the House Report explained, the Act "simply requires honesty of labeling." *Id.* Thus, the Act targeted manufacturer communications to prospective purchasers, not unstated manufacturer desires. In accordance with its limited purpose, the 1906 Act further limited federal regulatory intervention by making the prohibitions of "adulteration" and "misbranding" turn on deviations between the *labeled* composi-

tion of an article and its *actual* composition. *See* §§ 8, 10, 34 Stat. at 770-71. Thus, "intent" as used in the 1906 Act necessarily arose from claims on the label. A broader definition of "intent" would have created the anomaly that a product would have been defined as a drug on a basis that could not be regulated, since only statements on a label could make a product "adulterated" or "misbranded." *See id.* A proper understanding of the limited scope of "intent" in the 1906 Act is important because its concept of "intended use" is the same as the concept of "intended use" codified in the modern FDCA.

In 1911, this Court ruled that the drug labeling provisions of the 1906 Act prohibited false statements about the identity of a drug product, but not false therapeutic claims. *See United States v. Johnson*, 221 U.S. 488, 497 (1911). In 1912, Congress passed the Sherley Amendment, which "prohibited curative or therapeutic effect[s] . . . which [are] false and fraudulent," *see* Pub. L. No. 62-301, 37 Stat. 416 (1912), thus preserving the focus on claims as the basis of regulation.

The 1906 Act employed the language "intended to be used"—not simply "used"—to ensure that only those products labeled as recognized medicines, or labeled with claims that justified viewing the products as medicines, would be regulated. The communicated grounds for sale were controlling, as FDA's predecessor agency confirmed when it addressed tobacco products in 1914:

Under the Food and Drugs Act, a drug is defined as any substance or mixture of substances, intended to be used for the cure, mitigation, or prevention of disease of either man or other animals. It, therefore, follows that tobacco and its preparations, *when labeled in such a manner as to indicate their use for the cure, mitigation, or prevention of disease, are drugs within the meaning of the act*, and, as such, are subject to the provisions thereof.

On the other hand, tobacco and its preparations which are not so labeled and are used for smoking or chewing or as snuff and not for medicinal purposes are not subject to the provisions of the act.

U.S. Dep't of Agriculture, Bureau of Chemistry, *Service and Regulatory Announcements*, "No. 13: The Status of Tobacco and its Preparations Under the Food and Drug Act," at 24 (1914) ("*Bulletin*").¹¹

B. The Food, Drug, and Cosmetic Act of 1938.

From 1933 to 1938, Congress debated bills that became the FDCA, Pub. L. No. 75-717, 52 Stat. 1040 (1938). The 1938 Act differed from the 1906 Act in critical ways, including the following:

- The concept of "misbranding" was expanded to include claims in the "labeling" as well as on the "label." See FDCA, § 502(a), 52 Stat. at 1050 (codified at 21 U.S.C. § 352(a)). "Labeling" includes "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." *Id.* § 201(m), 52 Stat. at 1041 (codified at 21 U.S.C. § 321(m)).¹²
- The definition of "drug" was expanded to include "articles . . . intended to affect the structure or any function of the body," *id.* § 201(g)(3), 52

¹¹ FDA argues that the words "and are used for smoking or chewing or as snuff and not for medicinal purposes" suggest that consumer use, in addition to claims, would create jurisdiction. However, the better reading of that clause—as confirmed by FDA's long post-1914 practice—is that consumer use is presumed to follow communicated claims.

¹² *Kordel v. United States*, 335 U.S. 345, 348 (1948), held that certain circulars and pamphlets were "labeling" because they were "used in the sale of the drugs." This ruling recognized that the FDCA focused on manufacturer claims communicated in the marketplace.

Stat. at 1041 (codified as amended at 21 U.S.C. § 312(g)(1)(C)), because (1) the prior definition of "drug" related only to treating "diseases," and thus did not encompass certain physiological conditions, such as obesity or shortness, and (2) consumers were vulnerable to fanciful claims of medical cure for such conditions.

- The parallel category of medical "devices," which employed the same "intended use" term of art, see *id.* § 201(h), 52 Stat. at 1041 (codified as amended at 21 U.S.C. § 321(h)), was created because the term "drug" did not apply to all therapeutic products.
- Finally, a requirement of premarket safety review of new drugs was added, see *id.* § 505, 52 Stat. at 1052-53 (codified as amended at 21 U.S.C. § 355).

The statute explicitly limited the scope of FDA premarket safety review to manufacturer claims, and manufacturers were *not* required to demonstrate safety for other uses. A manufacturer had to demonstrate only that its new drug was safe "for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(d)(1). The Senate Report on one of the bills that led to the 1938 Act, paralleling the 1914 statement in the *Bulletin*, *supra* p. 10, recognized the continuing tie between manufacturer claims and FDA jurisdiction:

The use to which a product is to be put will determine the category into which it will fall. . . . *The manufacturer of the article through his representations in connection with its sale can determine the use to which the article is to be put.*

S. Rep. No. 73-493, at 2-3 (1934). Both FDA and the courts have relied widely upon this statement. See, e.g.,

56 Fed. Reg. 60,537, 60,546 (1991); *ASH v. Harris*, 655 F.2d 236, 238-39 (D.C. Cir. 1980); *United States v. An Article . . . "Sudden Change,"* 409 F.2d 734, 739 n.3 (2d Cir. 1969).

C. The Drug Amendments of 1962.

In 1962, Congress again expanded the scope of FDA's regulatory oversight. It required a manufacturer of a drug product to make a premarket showing of effectiveness, as well as safety, *for each "use . . . prescribed, recommended, or suggested in the labeling thereof."* Pub. L. No. 87-781, § 102(c), 76 Stat. 780, 781-82 (codified at 21 U.S.C. § 355(d)(1)).¹³ Congress made it a violation of the law to market any new drug with an "intended use"—*i.e.*, a use "prescribed, recommended, or suggested in the labeling"—not approved by FDA. *See* 21 U.S.C. §§ 321(p), 331(d), and 355(a). Thus, FDA must now determine that a new drug is safe and effective for *each* "intended use" before permitting it to be marketed. *Id.* § 355(d); *see also id.* § 352(f)(1); FDA Br. at 27 n.5 (all intended uses must be in labeling).

The Senate Committee that drafted the 1962 Amendments considered whether proof that a drug is effective for one "intended use" should permit it also to be promoted for other "intended uses." The Senators discussed the issue of different "intended uses" in terms of "claims":

A question arose as to the circumstances and extent to which a new claim or change of claim for effectiveness made after the initial approval of a new-drug application could be made without supporting

¹³ The effectiveness requirement involved parallel amendments to a number of FDCA provisions: the definition of "new drug," 21 U.S.C. § 321(p)(1); the criteria for new drug applications, *id.* §§ 355(b)(1)(A), 355(d)(5); the criteria that govern FDA's decision to withdraw approval of a new drug application, *id.* § 355(e)(3); and the investigational new drug exemption, *id.* § 355(i).

evidence to be submitted to the Department under the new-drug procedure. In order to eliminate any possible ambiguity on this point, the term "effectiveness" is incorporated in the committee's substitute amendment. The effect of this change is to require that *all claims for effectiveness*, whether made initially in a new-drug application or at any time thereafter, *must be supported by "substantial evidence,"* which term is defined in the substitute amendment.

S. Rep. 87-1744, pt. 2, at 5 (1962).

The outcome described in the Senate Report is codified in 21 U.S.C. § 355(d)(5), which requires a showing of effectiveness for all "conditions of use prescribed, recommended, or suggested in the [drug's] labeling," and in FDA's regulations. *See* 21 C.F.R. § 201.128. If a manufacturer prescribes, recommends, or suggests a new "intended use," it creates a different new drug, *see id.* § 310.3(h)(4), for which a separate approval must be obtained under 21 U.S.C. § 355(a). To obtain such approval, a manufacturer must submit to FDA, pursuant to 21 C.F.R. § 314.70(b)(3), a supplemental new drug application with "substantial evidence" showing that the product is effective and safe for the new "intended use," a use which must be "prescribed, recommended, or suggested in the [drug's] labeling," *i.e.*, claimed.

The 1962 congressional debate made clear that the phrase "use under the conditions prescribed, recommended, or suggested in the labeling" was synonymous with the concept of an "intended use." For example, the bill which became the 1962 Amendments proposed to require a drug to be safe "and effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling." *See* S. 1552, § 4(a)(1) (as introduced). Senator Kefauver, the bill's sponsor, said that his bill would assure "that all prescription drugs are safe and efficacious *for the uses for which they are intended.*" 107 Cong. Rec.

S5640 (daily ed. Apr. 12, 1961) (introducing S. 1552). Similarly, Chairman Harris of the House Commerce Committee described his bill, which included the identical provision requiring drugs to be safe and effective under the conditions claimed in the labeling, as requiring "a showing that new drugs and biologicals are effective *for their intended use*—as well as safe—before they may be marketed." 108 Cong. Rec. H7714 (daily ed. May 3, 1962) (Chairman Harris' remarks on H.R. 11581, Title I, Part A, § 102 (as reported)). *See also id.* at H10839 (daily ed. June 18, 1962) (Statement of Rep. Sullivan).

The Secretary of Health, Education, and Welfare ("HEW"), FDA's parent agency, testified that Chairman Harris' bill—which contained the provision concerning conditions claimed in labeling—would operate "by requiring that new drugs be shown effective for their intended uses, as well as safe, before they are marketed." *Drug Industry Act of 1962: Hearings on H.R. 11581 Before the House Comm. on Interstate and Foreign Commerce*, 87th Cong. 61 (1962) (Statement of HEW Secretary Ribicoff) ("1962 House Hearings"). Likewise, during hearings on S. 1552, Secretary Ribicoff stated that HEW supported the legislation because "[t]he manufacturer should satisfy FDA that his product is effective for the purposes claimed before it is marketed." *Drug Industry Antitrust Act of 1962: Hearings Before the Subcomm. on Antitrust and Monopoly of the Senate Comm. on the Judiciary*, 87th Cong. 2583 (1962) (Statement of HEW Secretary Ribicoff).

The Senate Committee Report said that the bill required "a premarketing showing that all new drugs are effective—as well as safe—for their intended uses." S. Rep. No. 87-1744, pt. 1, at 8 (1962). The House Committee Report stated that, if "the drug is generally recognized by experts to be effective for the conditions for which it is intended, it is not a new drug." H.R. Rep.

No. 87-2464, at 8 (1962). Thus, both reports equated "intended uses" with uses claimed in labeling. As the Conference Report acknowledged, "Both the House amendment and the Senate bill required . . . substantial evidence (as defined) of the *effectiveness of the drug for its proposed use*." H.R. Conf. Rep. No. 87-2526, at 19 (1962). Similarly, FDA's own comments stated:

The committee has heard testimony about the alleged difficulties of establishing whether a drug will or will not accomplish *its intended purpose*. . . . The drug companies routinely assert through promotional material, in labeling and by other means what they believe their products will accomplish. They do not hesitate to make claims. *The only question is whether they should justify these claims or show the facts upon which they are based.*

1962 House Hearings, at 571-72 (Written Comments of George P. Larrick, FDA Commissioner). Thus, both Congress and FDA equated manufacturer assertions with claims and "intended uses."

D. The Medical Device Amendments of 1976.

In 1976, Congress overhauled the FDCA's regulatory regime for medical devices. *See* Pub. L. No. 94-295, 90 Stat. 539 (1976). For "devices intended for human use," Congress established a risk-based classification system, *see* 21 U.S.C. § 360c(a)(1), which requires that certain devices obtain premarket approval for each of their "intended uses." *Id.* §§ 360c(a)(1)(C), 360e(c). As it did in the 1962 Drug Amendments, Congress allowed manufacturers to determine the "intended uses" for which premarket approval would be required.

Congress recognized that the expensive and time-consuming premarket approval requirement could restrict competition by new manufacturers. It authorized FDA to give clearances to "substantially equivalent" follow-on de-

vices as long as they claim *only* the "intended uses" approved for the pre-existing devices they imitate. *See id.* §§ 360c(f)(3), 360c(i)(1)(A). *See also* Food and Drug Administration, Guidance Doc. No. K86-3, *Guidance on the Center for Devices and Radiological Health's Pre-market Notification Review Program*, at 7 (1986) ("if a device [seeking a substantial equivalence clearance] has a different "intended use," there is no reason to proceed further to decide whether the devices are substantially equivalent").

Because the 1976 classification system and premarket approval and clearance regime applied only to "devices intended for human use," 21 U.S.C. § 360(k), concern was expressed that a manufacturer who was denied approval might relabel a device for veterinary use but market it for human use. As the FDA's Brief points out, the House Report sought to foreclose such evasion:

[A] manufacturer of a device that is banned [for human use cannot] escape the ban by labeling the device for veterinary use. The Secretary may consider the ultimate destination of a product in determining whether or not it is for human use, just as he may consider actual use of a product in determining whether or not it is a device.

FDA Br. at 28 (quoting H.R. Rep. No. 94-853, at 14 (1976)) (emphasis added in FDA Brief). The FDA Brief argues that this comment establishes that the FDCA's definitions of "drug" and "device" do not "limit[] the 'intended' effects of a product to those the manufacturer expressly claims." *Id.* at 27. However, the House Report does not eliminate the need for claims; it merely confirms that "claims" can be interpreted in context, *e.g.*, ostensible farm animal claims on a product sold in city pharmacies actually may imply a human use. Additionally, because the tobacco regulations do not identify or rely upon any manufacturer claims, either express or implied, and be-

cause FDA's assertion of jurisdiction does not rely on such claim interpretation, *see supra* p. 3 and note 6, this point is inapplicable.¹⁴ In fact, FDA comprehensively reviewed the legislative history of the 1976 Amendments in its 1980 administrative determination that it had no jurisdiction over cigarettes. *See* Letter from Mark Novitch for Jere E. Goyan, FDA Commissioner, to John F. Banzhaf, III and Peter N. Georgiades (Nov. 25, 1980). FDA there concluded that the legislative history provided "no evidence" to sustain its jurisdiction. *Id.* at 3.

E. The Drug Price Competition and Patent Term Restoration Act of 1984.

In the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), Congress authorized an "abbreviated new drug application" ("ANDA") procedure. This procedure permits the manufacturer of a generic version of a previously approved pioneer drug to avoid the expensive and time-consuming testing and review required to obtain approval of a standard "new drug application" ("NDA"). *See* 21 U.S.C. § 355(j). The ANDA process, like the substantial equivalence clearance process for a follow-on medical device, is intended to enhance competition and reduce health-care costs.¹⁵ FDA may not approve an ANDA unless "the labeling proposed for the new drug is *the same* as the labeling approved for the [pioneer] drug." *Id.* §355

¹⁴ Moreover, because the 1976 Committee Report interprets language enacted 38 years earlier, it is entitled to little weight. *See, e.g., Public Employees Retirement Sys. v. Betts*, 492 U.S. 158, 168 (1989).

¹⁵ The 1984 amendments do *not* change the provisions of the FDCA requiring FDA to approve *each* "intended use" before a drug is commercially distributed. *See, e.g.,* 21 U.S.C. § 355(d). Thus, if a proposed generic drug has an "intended use" that has not been approved for use in the labeling of the pioneer drug, the generic cannot be approved by an ANDA for any use.

(j)(2)(A)(v). *See* H.R. Rep. No. 98-857, pt. 1, at 21 (1984) ("an ANDA may not be approved for a condition of use that has not previously been approved for a [pioneer] drug"). As in the case of devices, however, pioneer drugs commonly have important unapproved ("off-label") uses that are foreseeable to the ANDA applicant and that may be predominant among consumers. Despite the probability that the generic product would be used for off-label uses, Congress permitted the generic manufacturer simply to duplicate the pioneer product's labeling. Thus, Congress again equated "intended uses" with labeled uses, *i.e.*, claimed uses.

F. The Medical Device Amendments of 1997.

In 1997, FDA asked Congress for authority to regulate off-label uses of devices. Congress refused to make such uses "intended uses." *See* Food and Drug Administration Modernization Act, Pub. L. No. 105-115, 111 Stat. 2296 (1997) ("FDAMA"). Instead, it temporarily authorized FDA, in reviewing a submission under 21 U.S.C. § 360(k), to require a manufacturer to include in the proposed labeling of its device a statement of "appropriate information" about an unclaimed use. FDAMA, § 205, 111 Stat. at 2337 (codified at 21 U.S.C. § 360c(i)(1)(E)(i)). *See id.* § 360c(i)(1)(E)(iv) (five-year sunset on FDA authority). Such a statement could be, for example, that there is insufficient information to justify the use. The unclaimed use still is not an "intended use." FDAMA amended the FDCA to include an explicit instruction that "[a]ny determination by [FDA] of the intended use of a device shall be based upon the proposed labeling." *Id.* § 360c(i)(1)(E)(i). *See* S. Rep. No. 105-43, at 27 (1997).¹⁶

¹⁶ Congress provided that the 1997 legislation would not "affect the question whether [FDA] has any authority to regulate tobacco." FDAMA, § 422, Pub. L. No. 105-115, 111 Stat. 2296, 2380 (1997) (codified at 21 U.S.C. § 321 note). Thus, the temporary au-

II. IN SHAPING THE MODERN FDCA, CONGRESS ACCEPTED FDA'S REPEATED AND CONSISTENT STATEMENTS, CONFIRMED BY THE COURTS, THAT MANUFACTURER CLAIMS WERE DETERMINATIVE OF "INTENDED USE."

Throughout the years that Congress was shaping the modern FDCA—by legislation in 1938, and with major amendments in 1962, 1976, and 1984—FDA consistently and repeatedly advised that manufacturer claims determined "intended use."

A. FDA Repeatedly Advised Congress That Communicated Manufacturer Claims Determine "Intended Use."

Since 1906, FDA has consistently advised Congress and others that only manufacturer statements establish "intended use." Indeed, many of FDA's statements about the meaning of "intended use" referred specifically to tobacco. The Department of Justice accurately summarized FDA's longstanding position in a 1980 brief defending FDA's determination that it lacked jurisdiction to regulate cigarettes:

In the 73 years since the enactment of the original Food and Drug Act, and in the 41 years since the promulgation of the modern Food, Drug, and Cosmetic Act, the *FDA has repeatedly informed Congress that cigarettes are beyond the scope of the statute absent health claims* establishing a therapeutic intent on behalf of the manufacturer or vendor.

* * * * *

[Even before the 1950's, there are many examples] of [FDA's] interpretation that cigarettes and related tobacco products are not a "drug" under the Act *except when there are health claims*, including correspondence between the agency and members of Congress. . . . These records, including correspond-

thority that FDA was given with respect to some unclaimed uses of devices is not available to FDA here.

ence dating from at least as early as 1940, show that the Commissioner's interpretation was in accordance with the contemporaneous construction of the 1938 Act by the persons charged with its administration.

Br. for Appellee, at 14, 22 n.19, *ASH*, 655 F.2d 236. Many examples of the FDA statements described in the *ASH* brief can be cited.

For instance, in 1965 hearings held in response to the 1964 Surgeon General's Report, FDA testified that it "has no jurisdiction under the Food, Drug, and Cosmetic Act over tobacco, *unless it bears drug claims.*" *Cigarette Labeling and Advertising, 1965: Hearings Before the House Comm. on Interstate and Foreign Commerce, 89th Cong. 193 (1965)* (Testimony of FDA Deputy Commissioner Rankin).

Similarly, in 1972 hearings before the Senate Committee on Commerce, the FDA Commissioner submitted a 1963 letter in which FDA's Bureau of Enforcement instructed all FDA Directors of Bureaus, Divisions, and Districts that "[t]he *statutory* basis for the exclusion of tobacco products from FDA's jurisdiction is the fact that tobacco marketed for chewing or smoking *without accompanying therapeutic claims*, does not meet the definitions . . . for food, drug, device or cosmetic." FDA Bureau of Enforcement, May 24, 1963, *reprinted in Public Health Cigarette Amendments of 1971: Hearings Before the Consumer Subcomm. of the Senate Comm. on Commerce, 92d Cong. 240 (1972)*. The Commissioner also testified that, "[i]n *Federal Trade Commission v. Liggett and Myers Tobacco Company* (108 F. Supp. 573, 1952), it was held that cigarettes are not drugs within the meaning of the act *unless a therapeutic purpose is claimed.*" *Id.* at 239.¹⁷

¹⁷ FDA's position was not and is not unique to tobacco. For example, in 1988, the Consumer Product Safety Commission

B. The Courts Consistently Confirmed That Communicated Manufacturer Claims Determine "Intended Use."

FDA's statements that "intended use" depends upon manufacturer claims have strong judicial support. The courts "have always read the . . . statutory definitions employing the term 'intended' to refer to specific marketing representations." *American Health Prods. Co. v. Hayes*, 574 F. Supp. 1498, 1505 (S.D.N.Y. 1983), *aff'd on other grounds*, 744 F.2d 912 (2d Cir. 1984). "The real test is how this product [is] being sold." *United States v. Nutrition Serv., Inc.*, 227 F. Supp. 375, 386 (W.D. Pa. 1964), *aff'd*, 347 F.2d 233 (3d Cir. 1965). As early as *Bradley v. United States*, 264 F. 79 (5th Cir. 1920), courts were holding that "intended use" is based upon claims. In 1953, the Second Circuit held that claims are essential to establish an "intended use." *FTC v. Liggett & Myers Tobacco Co.*, 203 F.2d 955 (2d Cir. 1953) (per curiam), *aff'g* 108 F. Supp. 573 (S.D.N.Y. 1952).¹⁸ See also *An Article . . . "Sudden Change,"* 409 F.2d at 739 n.3 ("[t]he manufacturer of the article, through his representations in connection with the article can determine the use").

("CPSC") asked FDA whether home exercise equipment was a medical device. The answer would determine which agency had jurisdiction, since drugs and devices subject to the FDCA are not subject to the Consumer Product Safety Act, 15 U.S.C. § 2052(a)(1)(H). In a letter from FDA to CPSC, FDA recognized that exercise equipment had foreseeable health uses—*e.g.*, "to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity"—that would render them medical devices *if claimed*. See Letter from FDA Chief Counsel Scarlett to CPSC General Counsel Lacy, at 2 (May 6, 1988) (lodged with the Clerk of the Court). However, FDA said that "home exercise products *for which no medical claims are made* should be regulated as consumer products by CPSC," *id.* (*i.e.*, that they are not FDCA devices).

¹⁸ The FDCA's definition of "drug" was imported wholesale into the FTC Act provision dividing responsibility between the FTC and FDA. Compare 21 U.S.C. § 321(g)(1) with 15 U.S.C. § 55(c). Thus, the definition had to have the same meaning in both acts.

In sustaining FDA's position that it lacks jurisdiction over tobacco products as customarily marketed, *ASH* described the "accepted . . . statutory interpretation" as follows:

the crux of FDA jurisdiction over drugs [lies] in manufacturers' representations as revelatory of their intent. ("The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put.") *Such an understanding has now been accepted as a matter of statutory interpretation.*

ASH, 655 F.2d at 238-39 (citation omitted).¹⁹

In the only two FDA enforcement actions against tobacco products, the manufacturers were making express claims of weight reduction, see *United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (D.N.J. 1959), or curing disease, see *United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes*, 113 F. Supp. 336 (D.N.J. 1953) (including common cold, influenza, pneumonia, scarlet fever, whooping cough, measles, meningitis, tuberculosis, and parrot fever). In each case, FDA's jurisdiction was based on claims. In particular, the *Trim* case showed that, by claiming a weight-control use to which (according to FDA) consumers put cigarettes generally, the product became subject to FDA jurisdiction that was not asserted over other brands. See *Trim*, 178 F. Supp. at 851. Claims, not foreseeable use, establish jurisdiction. FDA's claims-based approach in these two cases is consistent with its longstanding interpretation of "intended use" as a claims-based concept.

¹⁹ Because FDA had shown no inclination to change its statutory interpretation, the court noted that it need not decide whether a change was permissible. See *ASH v. Harris*, 655 F.2d 236, 242 n.10 (D.C. Cir. 1980).

To avoid these precedents, FDA's brief seeks to shore up its argument by relying on dicta in several cases that the "intended use" of a product may "be determined from its label, accompanying labeling, promotional material, advertising and *any other relevant source*." FDA Br. at 28. Each of the cases, however, involved express promotional claims. Further, under the canon of *noscitur a sociis*, "any other relevant source also must relate to claimed uses. See *Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995) (citing the canon of *noscitur a sociis* "to avoid ascribing to one word a meaning so broad that it is inconsistent with its accompanying words, thus giving unintended breadth to the Acts of Congress"). What makes the "other . . . source" relevant is that it is based on manufacturer claims (e.g., statements by sales representatives to potential customers). See *United States v. Articles of Drug for Veterinary Use*, 50 F.3d 497, 500 (8th Cir. 1995).²⁰

The case upon which FDA relied in its rulemaking for its new interpretation of "intended use" suggested in dictum that an "intended use" might be established by evidence that high-dose vitamins (i) were used "almost exclusively for therapeutic purposes," when (ii) "coupled with lack of a recognized nutritional [i.e., non-drug] use." *National Nutritional Foods Ass'n*, 557 F.2d at 334. FDA cited this dictum, but did not show how it could be derived from the text of the FDCA. In any event, the two premises upon which the dictum is based are not present here. FDA did not find that tobacco products have no

²⁰ FDA previously rejected consumer use as an independent basis for "intended use." FDA denied a petition that it regulate cigarettes as drugs on the basis of how "cigarettes are used by smokers." FDA said that evidence of consumer use was "no evidence" of the uses intended by manufacturers within the meaning of the FDCA's definitions. See Letter from Donald Kennedy, FDA Commissioner, to John F. Banzhaf, III (Dec. 5, 1977). FDA's position was affirmed in *ASH*, *supra* note 19.

recognized non-drug uses; it merely found the non-drug uses to be "secondary." And, although FDA asserts that one of the "drug-like" uses of tobacco—to sustain addiction—is "nearly exclusive," it equates that phrase with the terms "predominant," "widespread," and "common." 61 Fed. Reg. at 44,807, 44,810-11, 45,192. In any event, the very court that originated the "nearly exclusive" concept held that a toxic effect such as addiction is not a basis for finding that a product is a drug or device. *See National Nutritional Foods Ass'n*, 557 F.2d at 334-35.²¹

In sum, as the court of appeals correctly noted, in the 93 years that "intended use" has been central to federal drug law, "no court has ever found that a product is 'intended for use' or 'intended to affect' within the meaning of the [Act] absent manufacturer claims as to that product's use." FDA App. at 19a.

C. The Administrative Examples Offered by FDA Do Not Establish a Different Institutional View of the Importance of Manufacturer Claims.

FDA does not deny that it generally regards manufacturer claims as determinative of "intended use." It asserts, however, that the agency on occasion has regulated products in the absence of claims. The *Industry Comments* lodged with the Court refute FDA's examples in detail. Briefly stated:

- Several of FDA's examples rest on the theory that a word had developed a secondary meaning that made an implied claim (e.g., "hormone," "sun-screen," and "fluoride"). Other examples rest on

²¹ FDA's contention that "consumer use can be relevant in determining manufacturer intent," FDA Br. at 28 (relying on *ASH*, *supra* note 19), is, of course, correct in that consumer understanding can help clarify ambiguous claims. But, as *ASH* makes clear, manufacturer claims are determinative, and common usage is relevant only insofar as it helps explain their meaning. *See ASH*, 655 F.2d at 238-40. As noted above, FDA does not here rely on any claims, express or implied.

express claims (e.g., cocaine substitutes and tinted contact lenses).

- One example depends on a listing of thyroid in a medical pharmacopoeia, thereby obviating the need for any "intended use," see 21 U.S.C. § 321(g) (1)(A) (thyroid); another involves the obligation of a drug manufacturer with an investigational approval to avoid uses outside the scope of the approval, *see* 21 C.F.R. § 312.50 (interferon).
- Still others are based on special sources of FDA authority outside the FDCA's drug and device provisions, such as FDA's non-claims-based jurisdiction over radiation emitting products such as sun lamps, *see* 21 U.S.C. §§ 360hh-360ss (no "intended use" standard), and the lenient "appearance-of-violation" standard for import detentions, *see id.* § 381(a).
- Some examples reflect only tentative FDA views (e.g., the proposed fluoride rule) or uncontested actions (e.g., warning letters concerning novelty condoms or khat) that do not represent FDA's institutional position, *see* 21 C.F.R. § 10.85 (advisory opinions).

None of the examples upon which FDA relies was judicially reviewed. However, when a seizure of a cocaine substitute did reach the courts, the court relied on manufacturer claims to establish "intended use." *See United States v. Storage Spaces Designated Nos. "8" and "49"*, 777 F.2d 1363, 1366-67, nn.5, 6 (9th Cir. 1985). Moreover, FDA never brought any of these examples to Congress' attention while it was enacting food and drug legislation over the decades. These miscellaneous examples culled from fifty-seven years of FDCA administration did nothing to shape the meaning of "intended use" in the FDCA, and thus they are not reliable or authoritative guides to the meaning of "intended use" in the FDCA.

D. FDA's "Intended Use" Regulations Are Consistent With FDA's Longstanding Position That Claims Are Determinative.

The FDA Brief seeks to rely on FDA's 1952 regulations defining the words "intended use (or words to that effect)" for labeling purposes. FDA Br. at 26-27 (citing 21 C.F.R. §§ 201.128, 801.4). FDA is correct that "intended use" has a consistent meaning throughout the FDCA. But the regulations do not support FDA's current interpretation.

FDA's 1952 regulations begin by stating that the controlling standard is "objective intent." 21 C.F.R. § 1.106(o) (1952). By contrast, ordinary concepts of intent are subjective. The distinctive concept of "objective intent" reflects that "intended use" is a term of art. Thus, FDA's current reliance on subjective intent is precluded under its own regulations.

The regulations make the special meaning of "intended use" clear by saying that objective intent may be "shown by labeling claims, advertising matter, or oral or written statements"—*i.e.*, claims. It may also be shown by the fact that an article is "offered and used for a purpose" not stated in its labeling or advertising. Mere use for such a purpose is not sufficient; the article must be both offered and used. In context, to "offer[] . . . for a purpose" means more than a physical delivery. It contemplates a claim about the "purpose" for which the offered article is to be used. The claim typically is communicated by oral or written "expressions" but, in the absence of any such "expressions," may be communicated through "the circumstances surrounding the distribution of the article."²²

²² Tobacco products typically are sold with express claims, and FDA did not make any finding that the circumstances surrounding the sale of tobacco products communicate any jurisdictional claim to consumers. Moreover, FDA does not rely on any claims, express or implied. *See supra* p. 3 and note 6.

None of FDA's new theories to establish "intended use"—foreseeability, subjective manufacturer knowledge, desire, or intent, internal manufacturer papers, or product design—appears in the regulations.

The final portions of the 1952 regulations address situations in which the manufacturer does not control the distribution chain. If a manufacturer sells to independent distributors and knows they will make drug claims, it is responsible for those claims. But, FDA made no finding, and makes no argument, that such distribution claims occur with tobacco products.²³

What "objective intent" means is shown by *Articles of Drug*, 50 F.3d 497. The dispute there involved whether a product used to nourish calves also had an "intended use" as a drug. In the warehouse where the product was seized, the government had found brochures that clearly claimed a drug use, *e.g.*, to treat scours. *See id.* at 500. The manufacturer could not plausibly deny that it subjectively foresaw and desired such a use. Indeed, it apparently claimed that drug use in other countries. It explained, however, that it had not yet distributed the brochures in the United States. *See id.* The court acknowledged that the manufacturer's "intended application" of its product could "be derived from any relevant source, including product labels and any promotional materials." *See id.* But it held that "[p]romotional materials are rele-

²³ For purposes of construing the FDCA, FDA's "intended use" regulations are important only as they bear on how Congress understood the concept of "intended use" as it shaped that Act. To our knowledge, FDA never suggested to Congress that the "intended use" regulations were inconsistent with its repeated statements that only claims could establish an "intended use" that would render tobacco products a drug or device, *supra* pp. 19-24, or with the view that important off-label uses do not give rise to "intended uses," *see infra* pp. 28-32. Now that Congress has embodied the "intended use" concept in the FDCA as a term of art, FDA must respect Congress' intent. *See supra* p. 7 and note 9 and *infra* pp. 36-38.

vant to intent [only] so long as they are currently being distributed" or still have a continuing effect after being distributed. *Id.*

In short, only objective intent as shown by claims communicated in the market determines "intended use." Sources such as internal documents that show subjective intent are not "relevant." Nothing in the 1952 regulations supports FDA's assertion of jurisdiction over tobacco products.

III. THE STRUCTURE AND PROPER OPERATION OF THE FDCA PRESUPPOSE THAT "INTENDED USE" IS BASED ON THE CLAIMS MANUFACTURERS COMMUNICATE TO PROSPECTIVE PURCHASERS.

A. Equating Foreseeable Use With "Intended Use" Would Frustrate Congress' Intent to Prevent FDA Interference With the Practice of Medicine.

The FDCA cannot function as Congress intended it if the link between claims and "intended use" is broken. As FDA has explained:

Congress did not intend FDA to interfere with the practice of medicine. Thus, once a drug is approved for marketing, FDA generally does not regulate how and what uses physicians prescribe the drug. A physician may prescribe a drug for uses or in treatment regimens or patient populations that are not listed in FDA-approved labeling.

More Information for Better Patient Care: Hearings on S. 1477 Before the Senate Comm. on Labor and Human Resources, 104th Cong. 82 (1996) (Statement of William B. Schultz, FDA Deputy Commissioner for Policy) ("Schultz Testimony"); 59 Fed. Reg. 59,820, 59,821 (1994) (FDA has long recognized that off-label uses are rational and beneficial); FDA, Use of Unapproved Drugs for Unlabeled Uses, Drug Bulletin, Apr. 1982, at 4-5 (same); FDA, Compliance Program Guidance Manual, Center for

Devices and Radiological Health Consumer Education Program, FY 92-93, Program No. 7382.900 pt. I, at 7 (1992) ("off-label uses" are "considered within the practice of medicine").

FDA recognizes that "off label uses of approved products are appropriate, rational, and accepted in medical practice. FDA knows that there are important off label uses of approved drugs." *Shultz Testimony, supra*, at 81. Indeed, the American Medical Association's Vice President for Science and Education has estimated that between forty and sixty percent of all prescriptions are for off-label uses. *See* Fran Kritz, *FDA Seeks to Add Drugs' New Uses to Labels*, Wash. Post, Mar. 29, 1994, Health (Magazine), at 11. "Off-label drug use is common, and even predominant in the treatment of cancer patients." U.S. General Accounting Office, Pub. No. GAO/PEMD-91-14, *Off-Label Drugs: Reimbursement Policies Constrain Physicians in Their Choice of Cancer Therapies*, at 40 (1991). Of the seventeen most commonly used anti-cancer drugs, five are used off-label at least seventy percent of the time. *See id.* at 22-23. Some off-label cancer uses constitute "state of the art treatment." *Id.* at 11. In the case of AIDS, experts report that between ninety and one hundred percent of pharmaceutical treatments, including the antiretroviral "cocktail" therapies, are off-label. *See* Kenneth P. Berkowitz *et al.*, *Congress Tries To Bridge The 'Label Gap' But Nobody Is Cheering*, Med. Mktg. & Media, Jan. 1998, at 39-40.

Congress had a compelling practical reason for structuring the FDCA to allow off-label uses—medicine simply moves faster than FDA possibly can:

New uses for drugs are often discovered after FDA approves the package inserts that explain a drug's approved uses. Congress would have created havoc in the practice of medicine had it required physicians to follow the expensive and time-consuming proce-

dure of obtaining FDA approval before putting drugs to new uses.

United States v. Algon Chem. Inc., 879 F.2d 1154, 1163 (3d Cir. 1989) (quoting *Chaney v. Heckler*, 718 F.2d 1174, 1180 (D.C. Cir. 1983), *rev'd on other grounds*, *Heckler v. Chaney*, 470 U.S. 821 (1985)). See William L. Christopher, *Off-Label Drug Prescription: Filling the Regulatory Vacuum*, 48 Food & Drug L.J. 247, 261 (1993) (FDA "could not review drugs . . . at a pace equal to that at which physicians discover beneficial off-label uses").²⁴

Two examples illustrate the point. First, on July 20, 1999, the *New England Journal of Medicine* posted on its Internet web site an article that would not be printed until a September issue. See Bertram Pitt, *The Effect of Spironolactone on Morbidity and Mortality in Patients with Severe Heart Failure*, 341 New Eng. J. Med. 709 (1999) <<http://www.nejm.org/content/pitt/lasp>>. The article reports that an old drug had proved so effective in preventing heart failure that the study had been interrupted to treat the control group. An accompanying editorial explained that the article was being released via the Internet so that physicians *immediately* could begin off-label use of this "therapeutic potential of an old drug." Karl T. Weber, *Aldosterone and Spironolactone in Heart Failure*, 341 New Eng. J. Med. 753 (1999) <<http://www.nejm.org/content/weber/lasp>>.

²⁴ Because of insurance reimbursement issues, many states have passed statutes endorsing the off-label use of drugs. For example, N.J. Stat. Ann. § 26:1A-36.9(g) provides:

"Off-label" use of FDA-approved drugs provides efficacious drugs at a lower cost. To require that all appropriate uses of a drug undergo approval by FDA may substantially increase the cost of drugs and delay or even deny patients' ability to obtain medically effective treatment. FDA approval for each use would require substantial expenditure and time to undergo the clinical trials necessary to obtain FDA approval.

Second, "baby aspirin" continues to be marketed even though it is "not usually for kids anymore," due to concern over Reye Syndrome. Rebecca D. Williams, *How to Give Medicine to Children*, FDA Consumer, Jan.-Feb. 1996, at 6, 9.²⁵ Today, the small pills primarily are taken by adults daily to reduce the risk of heart attack. To avoid making reduction of heart attack an "intended use," however, baby aspirin manufacturers do not claim it. The Bayer Corporation now markets a baby sized (81mg.) tablet as "Aspirin Regimen Bayer," an "Adult Low Strength" product, labeled "for temporary relief of minor aches and pains or as recommended by your doctor." See Physicians' Desk Reference for Nonprescription Drugs and Dietary Supplements 607 (20th ed. 1999). On October 23, 1998, FDA approved professional labeling for the physician-supervised daily administration of aspirin to prevent heart attacks *in persons who already have suffered a heart attack*. See 63 Fed. Reg. 56,802 (1998). However, that use remains off-label and unapproved for over-the-counter aspirin products. See *id.* at 56,809. Moreover, for those who have not had a heart attack, the daily prophylactic use of baby aspirin is off-label even if given by a doctor's prescription.

Off-label uses of spironolactone and baby aspirin are foreseeable.²⁶ In the case of baby aspirin, off-label use is "predominant" and most likely "nearly exclusive" for over-the-counter sales. Under FDA's new theory of "intended use," these foreseeable and important uses would be "intended uses," would make spironolactone and baby aspirin misbranded and therefore unlawful, see 21 U.S.C. § 331

²⁵ FDA Consumer is a magazine published by FDA.

²⁶ FDA regulations generally require manufacturers that hold new drug approvals to monitor the literature regarding their products. See 21 C.F.R. § 314.80(b). Moreover, under product liability principles, drug manufacturers generally are held to the standard of experts on their products. See *Barson v. E.R. Squibb & Sons, Inc.*, 682 P.2d 832, 835-36 (Utah 1984).

(a), because their labels say nothing about these uses, *see id.* § 352(f)(1), and would expose the manufacturers to possible criminal liability, *see id.* § 333(a)(1). If FDA's new theory were to prevail, Congress' goal of avoiding FDA regulation of the practice of medicine would be thwarted.

B. Treating Foreseeable Use as "Intended Use" Would Frustrate the Premarket Approval Processes Enacted by Congress.

Under 21 U.S.C. § 355(d), FDA cannot approve a drug unless *all* of its "intended" uses first are proved safe and effective. The same is true for devices. *See id.* § 360e(d)(2). Under FDA's present theory, no drug or device approval could be granted until *every* foreseeable use was tested and supported. This would wreak havoc on drug and device approvals.

Many drugs and devices originate, or are first approved and used, outside the United States. By the time FDA approval is sought, a range of uses may be documented in the public medical literature. However, some uses are far more difficult to test than others, and some may not appear economically significant enough to justify the considerable expense of separate testing. *See* Michael P. VanHuysen, Note, *Reform of the New Drug Application Process*, 49 Admin. L. Rev. 477, 488-89 (1997). Cost constraints often force manufacturers to target only a few key uses for testing and approval, even though other foreseeable uses may merit supplemental testing and approval.²⁷ Thus, it may be appropriate for a manufacturer to claim only one or a few uses initially, and to accept the concomitant limits on its labeling claims. Important uses of a new drug or device also may emerge during the often lengthy period of FDA review. *See Algon Chem.*, 879 F.2d at 1163.

²⁷ A manufacturer may advertise its product only for its approved, labeled uses. *See* 21 C.F.R. § 202.1(e)(4)(i)(a).

In December 1998, FDA approved LYMERix, a vaccine for a potentially serious tick-borne disease, but approved it only for use in persons *from ages 15 to 70*. *See* Carol Lewis, *New Vaccine Targets Lyme Disease: New Hope for Diminishing 'Great Masquerader,'* FDA Consumer, May-June 1999, at 12-13. This "intended use" was approved even though "the highest reported rates of Lyme disease are in children 2 to 15 years old." *Id.* at 13. The manufacturer now is studying the vaccine in children. *See* Linell Smith, *Fighting Lyme Disease With a New Vaccination*, Baltimore Sun, June 20, 1999, Home and Family, at 1M. There are no reports or plans to test the drug in persons over seventy, but physicians nonetheless are making it available off-label to those over seventy where they are at risk. *See id.* By permitting the manufacturer of LYMERix to limit its "intended use" to adults, the FDA made the vaccine available more quickly, with over 700,000 doses administered as of June, 1999. *See id.* Under FDA's new view of "intended use," however, the vaccine still would be unavailable because not all foreseeable (and therefore "intended") uses have been approved, or even yet applied for.

C. Expanding "Intended Use" Beyond Claimed Use Would Limit Generic Competition.

The ANDA process to obtain expedited approval of a generic drug, *see* 21 U.S.C. § 355(j), and the substantial equivalence clearance process for follow-on devices, *see id.* §§ 360(k), 360c(f), 360c(i), limit the "intended uses" that may be claimed. The labeling of a generic drug seeking ANDA approval must be substantially identical to that of the pioneer drug. *See id.* §§ 355(j)(2)(A)(v), 355(j)(4)(G); 21 C.F.R. § 314.94(a)(3). A follow-on device must be "substantially equivalent" to the pioneer device, *see* 21 U.S.C. § 360c(f)(1)(A), and have the same "intended use," *see id.* § 360c(i)(1)(A); 21 C.F.R. § 807.92(a)(5). Otherwise, FDA must deny

approval or clearance. See 21 U.S.C. §§ 355(j)(4)(G), 360c(i). Thus, a generic or follow-on product is prohibited from having any "intended uses" (i.e., claimed indications) that are not approved for the pioneer product and supported by its labeling.

But circumstances at the time a follow-on application is submitted—generally at the end of the period of patent exclusivity—may be very different from those when the pioneer product entered the market. The medical community's experience with the product often spawns important off-label uses.²⁸ Indeed, off-label uses now may be predominant, because the original "intended use" may have become largely obsolete, e.g., baby aspirin.

This circumstance presents no problem under the traditional concept of "intended use." As long as the follow-on product does not claim an off-label use in its labeling, the off-label use is not an "intended use," regardless of how foreseeable, common, or desired it may be. Thus, the off-label use does not require separate FDA approval.

By contrast, under FDA's new theory, foreseeable, common, or desired off-label uses automatically are "intended uses," regardless of what the manufacturer claims. A dilemma results. FDA cannot approve a follow-on drug or device until *all* of its "intended uses" are supported by its labeling. See *id.* § 352(f)(1), 21 C.F.R. §§ 201.5, 201.100(c)(1), 801.5, 801.109(c). Yet, FDA cannot approve the follow-on product if its labeled uses differ from those of the pioneer. See 21 U.S.C. §§ 355(j)(2)(A)(v), 355(j)(4)(G) (drugs); *id.* §§ 360(k), 360c(i), 21 C.F.R. § 807.92(a)(5) (devices); *see also* 21 U.S.C. § 360c(i)(1)(E)(iv) (substantial equivalence for devices). Of course, the manufacturer of a generic drug or

²⁸ One such situation is described in *In re Orthopedic Bone Screw Liability Litigation*, 159 F.3d 817 (3d Cir. 1998), *pet. for cert. filed*, 67 U.S.L.W. 3684 (U.S. May 3, 1999) (No. 98-1768).

device could opt to incur the expense and delay of a full new drug application or device premarket approval application, but that approach would defeat the goals of the generic drug approval and substantial equivalence clearance processes. Thus, applied faithfully, FDA's new theory would frustrate the operation of the FDCA's provisions and lead to results contrary to Congress' intent of increasing competition and reducing health care costs.

D. These Problems Cannot Be Cured by FDA's Enforcement Discretion.

To avert these difficulties, FDA might seek to invoke "enforcement discretion" to allow the continued marketing of drugs and devices with unapproved "intended uses," just as it seeks to allow continued sale of tobacco products despite finding them unsafe. Such a regime would be unlawful. See, e.g., *Chaney*, 470 U.S. at 833-34 (agency cannot suspend a statute); *Hoffman-LaRoche, Inc. v. Weinberger*, 425 F. Supp. 890, 894 (D.D.C. 1975) (same).

Even if those difficulties could be surmounted, however, the FDCA has important consequences that are not subject to FDA control. For example, a violation of the FDCA may be a predicate for a state-law tort claim.²⁹ In addition, challengers to FDA's approvals and clear-

²⁹ See, e.g., *Talley v. Danek Med., Inc.*, 179 F.3d 154, 160-61 (4th Cir. 1999); *In re Bendectin Litig.*, 857 F.2d 290, 313 (6th Cir. 1988); *Stanton by Brooks v. Astra Pharm. Prods. Inc.*, 718 F.2d 553, 563 (3d Cir. 1983). One example is currently awaiting a decision on petition for a writ of *certiorari*. See *Bone Screw Liab. Litig.*, *supra* note 28. In that case, FDA refused to clear a § 360(k) notification for a product with labeling claiming an established off-label use, but it cleared an amended notification that included only the established labeled uses of the pioneer device. Later, the manufacturer's omission of a foreseen and desired off-label use was held actionable under a state-law tort theory of "fraud on the FDA."

ances could use FDA's new theory of "intended use" to disrupt the current approval process. *See, e.g., Sero Laboratories, Inc. v. Shalala*, 158 F.3d 1313, 1316-17 (D.C. Cir. 1998). Thus, FDA's reliance on agency "discretion" would provide no solution.

IV. BECAUSE FDA'S NEW THEORY OF "INTENDED USE" SUBVERTS THE WILL OF CONGRESS, CONFLICTS WITH THE FDCA, AND RENDERS IT UNWORKABLE, THE REGULATIONS BASED THEREON ARE CONTRARY TO LAW AND VOID.

FDA's claim that statutory analysis begins and ends with the isolated words of the FDCA's drug and device definitions simply is incorrect. In *Commissioner v. Engle*, 464 U.S. 206 (1983), the Commissioner of Internal Revenue similarly had based his statutory interpretation on a single provision of the tax code, without regard to its context or effect on other provisions. This Court rejected the Commissioner's simplistic approach:

The true meaning of a single section of a statute in a setting as complex as that of the revenue acts, however precise its language, cannot be ascertained if it be considered apart from related sections, or if the mind be isolated from the history of the . . . legislation of which it is an integral part.

Id. at 223. *Engle* holds that the "duty" of courts and agencies is "to find that interpretation which can most fairly be said to be imbedded in the statute, in the sense of being most harmonious with its scheme and with the general purposes that Congress manifested." *Id.* at 217. *See also Gustafson*, 513 U.S. at 569 (the "Act is to be interpreted as a symmetrical and coherent regulatory scheme"); *FTC v. Mandel Bros.*, 359 U.S. 385, 389 (1959) ("our task is to fit, if possible, all parts into a harmonious whole").

An important element of harmony is *consistency*. This Court has resisted theories of statutory construction that require giving inconsistent meanings to the same words in the same statute. *See United States Nat'l Bank of Oregon v. Independent Ins. Agents, Inc.*, 508 U.S. 439, 460 (1993); *BankAmerica Corp. v. United States*, 462 U.S. 122, 129 (1983). It also has avoided attributing new meanings to terms with settled, widely understood, and relied-upon definitions. *See id.* at 130-32. Where, as here, "the business community directly affected *and* the enforcing agencies *and* the Congress have read [a] statute the same way for 60 years," *id.* at 132, interpretive consistency has a powerful claim.

As shown above, the concept of "intended use" has a long history and a settled term-of-art meaning that is deeply imbedded in the FDCA. When that accepted meaning is honored and applied, the Act functions harmoniously as Congress intended. When it is rejected, there is disharmony and inconsistency, and the will of Congress is thwarted. As *Brown & Williamson* demonstrates, Congress has not only ratified FDA's construction of "intended use,"³⁰ but, as in *Engle*, Congress has incorporated that meaning into the Act itself.³¹

FDA argues that, under *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837 (1984), it may adopt any plausible meaning of a statutory phrase on which it relies. *See FDA Br.* at 19-20. The premise that any *Chevron* deference

³⁰ *See Morton v. Ruiz*, 415 U.S. 199, 237 (1974) ("too late now" for agency to change interpretation after it consistently "led Congress to believe" that interpretation); *see also NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 274-75 (1974) ("a court may accord great weight to the longstanding interpretation placed on a statute by an agency charged with its administration"); *United States v. Rutherford*, 442 U.S. 544, 554 n.10 (1979).

³¹ *See also cases cited supra* note 9.

applies here is erroneous. What FDA attempts here is not mere gap filling or even a routine application of a jurisdictional standard. Rather, it is a quantum regulatory expansion of jurisdiction over an entire industrial sector. The FDA Brief cites no comparable circumstance that was resolved by *Chevron* deference, and we know of none. *Cf. St. Luke's Hosp. v. Secretary of HHS*, 810 F.2d 325, 331 (1st Cir. 1987) (discussing limits of *Chevron*). Moreover, even if FDA's change in position were not entirely "fatal" to its claim of deference, *see Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. 735, 742 (1996), it necessarily weakens any such claim, *see INS v. Cardoza-Fonseca*, 480 U.S. 421, 446 n.30 (1997) ("agency interpretation of a relevant position which conflicts with the agency's earlier interpretation is entitled to considerably less deference than a consistently held agency view").

Finally, a similar deference argument was made in *Engle*, a case decided the same term as *Chevron*, and this Court flatly rejected it. The Court held that the deference "principle [only sets] the framework for judicial analysis; it does not displace it." 464 U.S. at 225. Where, as here, the history and internal logic of a statute show that Congress intended a special meaning, there is simply no room for deference. *See Chevron*, 467 U.S. at 842-43 (both courts and agencies are bound by the clear will of Congress). FDA's attempt to exceed its settled jurisdictional authority by inventing a new meaning for "intended use" is contrary to the understanding of "intended use" imbedded in the definitions of "drug" and "device" and throughout the FDCA.

CONCLUSION

As Congress builds a complex statute such as the FDCA, later provisions come to rest on the foundational concepts already laid down. Early concepts become imbedded in the Act, and are essential to its operation. They are defined and limited by their functions and interconnections. A statute must be read as an organic whole, and the foundational terms must be given a consistent meaning that permits the harmonious functioning of the Act as a whole.

FDA has not approached the FDCA in this fashion. Instead, it has abstracted the definitions of "drug" and "device" from a complex 93-year statutory context. FDA construes the core statutory concept of "intended use" as if it were a fragment scrawled on a wall, and assigns to it a meaning that frustrates congressional intent. The Court should repudiate FDA's opportunism, and require FDA to respect the law Congress has written.

The decision of the Court of Appeals should be affirmed.

Respectfully submitted,

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Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, *et al.*,
v. *Petitioners,*

BROWN AND WILLIAMSON TOBACCO CORP., *et al.*,
Respondents.

On Writ of Certiorari to the
United States Court of Appeals
for the Fourth Circuit

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QUESTION PRESENTED

Whether the Food and Drug Administration ("FDA") has jurisdiction to regulate tobacco products even though Congress did not intend for FDA to regulate tobacco products when it enacted the Federal Food, Drug, and Cosmetic Act, and Congress—having been repeatedly advised by FDA that it lacks jurisdiction—enacted a series of tobacco-specific statutes addressing tobacco and health, which give no role to FDA and are inconsistent with FDA's assertion of jurisdiction?

RULE 29.6 LISTING***Philip Morris Incorporated***

The parent company of Philip Morris Incorporated is Philip Morris Companies, Inc. Philip Morris Incorporated has no nonwholly owned subsidiaries.

Lorillard Tobacco Company

The parent companies of Lorillard Tobacco Company are Lorillard, Inc., and Loews Corporation. Lorillard Tobacco Company has no nonwholly owned subsidiaries.

PARTIES TO THE PROCEEDINGS

The petitioners are: Food and Drug Administration, and Jane E. Henney, Commissioner of Food and Drugs.

The respondents are: Brown and Williamson Tobacco Corporation; Lorillard Tobacco Company; Philip Morris Incorporated; R.J. Reynolds Tobacco Company; Coyne Beahm, Incorporated; National Association of Convenience Stores; ACME Retail, Incorporated; United States Tobacco Company, LP; Conwood Company, LP; National Tobacco Company, LP; Pinkerton Tobacco Company, LP; Swisher International, Incorporated; Central Carolina Grocers, Incorporated; J.T. Davenport, Incorporated; North Carolina Tobacco Distributors Committee, Incorporated; The American Advertising Federation; American Association of Advertising Agencies; Association of National Advertisers, Incorporated; Magazine Publishers of America; Outdoor Advertising Association of America, Incorporated; and Point of Purchase Advertising Institute.

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IN THE
Supreme Court of the United States

No. 98-1152

FOOD AND DRUG ADMINISTRATION, *et al.*,
v. *Petitioners,*

BROWN AND WILLIAMSON TOBACCO CORP., *et al.*,
Respondents.

On Writ of Certiorari to the
United States Court of Appeals
for the Fourth Circuit

BRIEF FOR RESPONDENTS
PHILIP MORRIS INCORPORATED
&
LORILLARD TOBACCO COMPANY

OPINIONS BELOW

The opinions below are identified in the Brief for the Government ("Pet. Br."), and printed in the Appendix to the Petition for Writ of Certiorari ("Pet. App.").

JURISDICTIONAL STATEMENT

This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

This case involves the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, the Federal Cigarette Labeling and Advertising Act ("FCLAA"), 15 U.S.C. § 1331 *et seq.*, the Comprehensive Smokeless Tobacco Health Education Act

("CSTHEA"), 15 U.S.C. § 4401 *et seq.*, and the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act ("ADAMHA Amendments"), 42 U.S.C. § 300x-26. These statutes are set forth in the Appendix to Respondents' Brief in Opposition to Petition for a Writ of Certiorari ("Opp. Cert. App.").

INTRODUCTION

In 1996, FDA declared that it has jurisdiction to regulate tobacco products under the FDCA, and issued regulations governing their labeling, advertising, and retail sale. Respondents challenged FDA's assertion of jurisdiction and its regulations. The district court held that the FDCA authorizes FDA to assert jurisdiction but invalidated FDA's advertising regulations. *See Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1397-1400 (M.D.N.C. 1997) (Pet. App. 76a). The United States Court of Appeals for the Fourth Circuit reversed on the threshold jurisdictional issue. It held that Congress never intended the FDCA to grant FDA jurisdiction over tobacco products as customarily marketed. *See Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155 (4th Cir. 1998) (Pet. App. 1a).

The question at issue is whether Congress granted FDA the authority to regulate tobacco products as customarily marketed.¹ The Government argues that this question is answered exclusively by the definition section of the FDCA. The court of appeals expressly disagreed, correctly concluding that this case can be decided only by looking at the statute as a whole and at Congress' histori-

¹ The phrase "as customarily marketed" refers to tobacco products with claims of "smoking pleasure" and similar claims, as opposed to health-benefit claims. *See e.g.* Letter from Acting FDA Comm'r Novitch for FDA Comm'r Goyan to Banzhaf, Jt. App. at 54. ("Novitch Letter") (Nov. 25, 1980). All references herein to "tobacco products" are to such products as customarily marketed.

cal treatment of tobacco and health. *Brown & Williamson*, Pet. App. at 14a. The Government ignores or trivializes that history. However, that "historical background . . . is essential to a proper interpretation of the Act's present text." *Department of Commerce v. United States House of Representatives*, 119 S. Ct. 765, 775 (1999). It shows unequivocally that Congress never intended to delegate to FDA the authority to regulate tobacco products, but chose instead to regulate those products itself through a series of tobacco-specific statutes.

SUMMARY OF ARGUMENT

Not satisfied with Congress' regulation of tobacco products, FDA set out in 1996 to create a new national tobacco policy. It announced that tobacco products fall within the FDCA's definitions of "drug" and "device" based on its finding that such products are "intended to affect the structure or any function of the body of man." 21 U.S.C. § 321(g)(1)(C) and (h)(3).² FDA took this action even though:

(1) When Congress enacted the FDCA in 1938, it did not intend for FDA to regulate tobacco products—such products are not among the several product categories to which the FDCA expressly applies, and Congress did not discuss or debate applying the FDCA to tobacco products;

(2) FDA's contemporaneous construction of the FDCA was that it lacked authority over tobacco products;

(3) Immediately after the 1964 Surgeon General's Report on smoking, FDA once again told Congress that it lacked authority over tobacco products, and advised Con-

² The brief filed by R.J. Reynolds Tobacco Company shows that the FDCA as a whole cannot be read to apply to tobacco products. The briefs filed by Brown and Williamson Tobacco Corporation and United States Tobacco Company, *et al.*, demonstrate why tobacco products do not meet these definitions.

gress that granting FDA such authority would likely result in a ban;

(4) Given this understanding, Congress *rejected* proposals to give FDA such authority and instead enacted the Federal Cigarette Labeling and Advertising Act ("FCLAA"), which requires congressionally-authored warnings on cigarette packages and reserves to Congress authority to address smoking and health;

(5) After enactment of the FCLAA, FDA expressed its understanding that Congress had reserved to itself the authority to regulate health issues regarding tobacco products, an understanding that Congress itself confirmed by exempting such products from the authority of other federal health agencies that had not, as had FDA, already disavowed jurisdiction over those products;

(6) As new information respecting tobacco and health was presented to Congress, it adopted additional legislation specifically regulating the labeling and advertising of tobacco products, and creating incentives for the States to control their retail sale—without providing any role for FDA;

(7) While acting upon tobacco-specific legislation and at other times, Congress considered, but never enacted, legislation to grant FDA authority over tobacco products.

In the face of this history, FDA nonetheless asks this Court to hold that, in 1938, Congress silently—indeed, unwittingly—authorized FDA to regulate and ban tobacco products. This position is contrary to FDA's disavowals of any authority over tobacco products, which it repeatedly communicated to Congress and which were a predicate for Congress' enactment of tobacco-specific statutes.

In these enactments, Congress expressly *reserved to itself* the power to regulate health issues regarding tobacco

products—either directly or by carefully delineating limited, non-policymaking roles for certain federal agencies—but provided no role for FDA. In legislating national tobacco policy, Congress has addressed the same aspects of tobacco-product labeling, advertising and sale that FDA now seeks to regulate by administrative fiat. FDA's assertion of jurisdiction neither fills a gap in the FDCA nor comports with the purpose or operative provisions of that Act. Rather, "[i]t is effectively the introduction of a whole new regime of regulation . . . which . . . is not the one that Congress established." *MCI v. AT&T*, 512 U.S. 218, 234 (1994).

Simply put, FDA's assertion of jurisdiction cannot be reconciled with Congress' policy as embodied in its tobacco-specific legislation. Congress and FDA itself repeatedly have recognized that a principled application of the "drug" or "device" provisions of the FDCA to tobacco products would result in their prohibition because tobacco products could not meet the Act's safety requirement. But a national ban on tobacco products—like many other aspects of FDA's assertion of jurisdiction—would directly and unavoidably conflict with the tobacco-specific legislation enacted by Congress.

The relevant history and these irreconcilable conflicts establish that Congress never intended that tobacco products be subject to the FDCA. In disregarding that intent, FDA has usurped Congress' legislative powers.

ARGUMENT

I. CONGRESS HAS NEVER GIVEN FDA AUTHORITY OVER TOBACCO PRODUCTS, BUT INSTEAD HAS CHOSEN TO REGULATE TOBACCO PRODUCTS IN WAYS THAT ARE FUNDAMENTALLY INCOMPATIBLE WITH FDA JURISDICTION.

FDA defends its assertion of jurisdiction with the remarkable claim that Congress always intended that FDA

could regulate tobacco products under the FDCA. *See* 61 Fed. Reg. 44,396, 45,253 (1996). Yet this claim makes pointless Congress' consideration for many years of who should regulate tobacco products and how. In fact, FDA repeatedly told Congress that the FDCA does not extend to tobacco products. Given this understanding, no fewer than thirty-six bills have been introduced in Congress to grant FDA jurisdiction over tobacco products, reflecting congressional understanding that new legislation would be necessary to confer such jurisdiction. But Congress never enacted such legislation.

Rather, after much discussion, Congress created its *own* legislative program specifically addressing the issue of tobacco and health. This legislation responds to the very concerns FDA relies on to justify its assertion of jurisdiction—youth access, the influence of tobacco advertising, and the pharmacological effects of tobacco products on the body, including nicotine “addiction.”

As FDA and the Justice Department acknowledged, “[t]he participants in these [congressional] discussions [on tobacco] . . . would be shocked to learn that during all this time FDA has had jurisdiction to regulate cigarettes as drugs, and presumably to ban them.” Brief for Gov’t Appellee (FDA) (“*FDA/DOJ Brief*”)³ at 40, *ASH v. Harris*, 655 F.2d 236 (D.C. Cir. 1980).

A. Federal Food and Drug Laws Were Never Intended to Cover Tobacco Products as Customarily Marketed.

The federal food and drug laws—and the view that they do *not* apply to tobacco products—go back nearly 90 years. In 1906, Congress passed the Pure Food and

³ Respondents have lodged with the Court a compilation of materials referenced herein, excluding judicial decisions, statutes, and regulations.

Drug Act, Pub. L. No. 59-384, 34 Stat. 768 (1906). Nothing in the language or legislative history of that early legislation indicates that Congress intended it to govern tobacco products. Indeed, FDA’s predecessor, the Bureau of Chemistry in the Department of Agriculture, announced that it could *not* regulate tobacco products unless they were marketed with medical claims. Bureau of Chemistry, U.S. Dep’t of Agriculture, *Service & Regulatory Announcements*, No. 13 (Apr. 2, 1914).

When this announcement was made, concerns about the health effects of tobacco were widespread, and scientific reports already had identified the pharmacological effects of nicotine.⁴ Between 1895 and 1921, fourteen states banned cigarettes entirely; and all the others prohibited their sale to minors.⁵ This Court upheld such a cigarette ban in *Austin v. Tennessee*, 179 U.S. 343, 348 (1900), observing that the “belief in [the] deleterious effects [of ‘cigarettes’] . . . has become very general.” *See also Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 513 (1992) (noting that “physicians had suspected a link between smoking and illness for centuries”). A few years later, some members of Congress proposed to amend the 1906 Act to cover tobacco products. *See* S. 1468, 71st Cong. (1929); 71 Cong. Rec. 2589 (1929). But that proposal—like every similar proposal since—was not enacted.

⁴ *See, e.g.*, Henningfield & Jasinski, *Pharmacologic Basis for Nicotine Replacement*, in *Nicotine Replacement: A Critical Evaluation* 35-36 (Pomerleau, *et al.* eds., 1988) (“[P]harmacologic studies of the physiologic actions of nicotine were well underway by the 19th century. By the beginning of the 20th century, there was little scientific question that nicotine was the pharmacologic mediator of many effects of tobacco sought by its users.”).

⁵ *See* Nuehring & Markle, *Nicotine and Norms: The Re-Emergence of a Deviant Behavior*, in 21 *Social Problems* 513, 515 (1974); 1899 Tex. Gen. Laws Ch. 139 § 1 (*codified at* Tex. Penal Code art. 1049 (1911)).

Nor did Congress intend to authorize FDA to regulate tobacco products when it enacted the FDCA in 1938. The FDCA identifies the four categories of products to which it applies: foods, drugs, devices, and cosmetics. Tobacco products are not among them, even though at the time of its enactment tobacco products outsold pharmaceuticals three-to-one, 37% of American adults smoked cigarettes, and tobacco excise taxes accounted for ten percent or more of federal tax revenues.⁶ Moreover, the federal government recognized tobacco as a separate sector of the economy. *See, e.g., U.S. Dept. of Commerce, Statistical Abstract of the United States*, 178-9 (1939). If Congress had intended the FDCA's "drug" and "device" provisions to encompass so significant a category as tobacco products, the legislative history surely would reflect it.

But there is *nothing* in the language or legislative history of the Act suggesting this intent. "If Congress intended such a result, its failure even to hint at it is spectacularly odd." *Medtronic v. Lohr*, 518 U.S. 470, 491 (1996). It is "not plausible to interpret the statutory silence as tantamount to an implicit congressional intent" that FDA regulate tobacco products. *Central Bank of Denver v. First Interstate Bank of Denver*, 511 U.S. 164, 185 (1994). Even the Government does not argue that Congress in 1938 envisioned that tobacco products were within the scope of the FDCA, and it concedes that there was "no discussion in the legislative history of the 1938 Act" respecting its potential application to tobacco products. Pet. Br.

⁶ U.S. Dep't of Commerce, Bureau of the Census, *Historical Statistics of the United States: Colonial Times to 1970*, 319 (H.R. Doc. No. 93-78, 1973); U.S. Dep't of Health and Human Services, Public Health Service, *The Health Consequences of Smoking to Women, A Report of the Surgeon General* 23 (1980); U.S. Dep't of Commerce, Bureau of the Census, *Statistical Abstract of the United States 1938*, at 179 (Table 181) (1939).

at 22, n.4.⁷ *Cf. Amoco Prod. Co. v. Southern Ute Indian Tribe*, 119 S. Ct. 1719, 1724-27 (1999) (examining the historical context of the relevant statute).

Had there been any suggestion in 1938 that the FDCA might apply to tobacco products:

Congress would have made it explicit in the statute, or at least some of the Members would have identified or mentioned it at some point in the unusually extensive legislative history "In a case where the construction of legislative language such as this makes so sweeping and so relatively unorthodox a change, . . . judges as well as detectives may take into consideration the fact that a watchdog did not bark in the night."

Chisom v. Roemer, 501 U.S. 380, 396, n.23 (1991). Indeed, the Senate and House Conference Committee managers supporting passage of the FDCA included Members from the two leading tobacco States—North Carolina and Kentucky. *See* 83 Cong. Rec. 9094 (1938).

Congress' silence cannot be attributed to a lack of legislative interest in tobacco. Since at least the turn of the century, Congress has regulated tobacco products separately from foods, drugs, devices, and cosmetics. *See, e.g., Pub. L. No. 57-237, §§ 1-2, 32 Stat. 714* (1902)

⁷ Far from creating an "overwhelming implication" that the FDCA covers tobacco products, Pet. Br. at 19, this congressional silence at most reflects Congress' understanding that tobacco products, like other non-medical products, are subject to the FDCA only if manufacturers or vendors make therapeutic claims. *See United States v. 35 1/2 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847, 848-49 (D.N.J. 1959); *United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes*, 113 F. Supp. 336, 337 (D.N.J. 1953). In the present case, FDA asserted jurisdiction "regardless of whether manufacturers make express claims of therapeutic value," Pet. Br. at 15, and FDA has not alleged that any of the respondents make such claims. 61 Fed. Reg. 44,396, 45,194 (1996).

(cigarette packaging); Pub. L. No. 61-5, §§ 30-35, 36 Stat. 108-11 (1909) (cigarette packaging, marketing, and sale); Pub. L. No. 73-483, §§ 1-13, 48 Stat. 1275 (1934) (cigarette production, marketing, and consumption); Pub. L. No. 74-314, §§ 2-3, 49 Stat. 731 (1935) (cigarette marketing). Congress even passed *separate* tobacco legislation in the same year it passed the FDCA. See Pub. L. No. 75-430, 52 Stat. 31 (1938). Thus, it is no surprise that the 1938 Congress “did not endeavor to break away from the traditional understanding,” *Murphy Bros., Inc. v. Michetti Pipe Stringing, Inc.*, 119 S. Ct. 1324, 1327 (1999), that tobacco products are separate from foods, drugs, devices, and cosmetics.

FDA’s original understanding that the FDCA does not cover tobacco products reflected its own extensive involvement in drafting the FDCA—preparing the initial bill, testifying on it and successor bills, and explaining to Congress how the “drug” and “device” definitions of the Act would operate.⁸ In light of that involvement, in the two decades following enactment of the FDCA, FDA consistently reiterated its understanding and “repeatedly informed Congress that cigarettes were not comprehended by the statutory definition of the term ‘drug’ absent

⁸ The “original bill leading to the enactment of the [FDCA] . . . was prepared in the U.S. Dept. of Agriculture,” which was the parent department of FDA (and FDA’s predecessor, the Bureau of Chemistry). Dunn, *Federal Food, Drug, and Cosmetic Act*, 24 (1938). See e.g., *Food, Drugs and Cosmetics: Hearing on S. 1944 Before a Subcomm. of the Senate Comm. on Commerce*, 73d Cong. 15-16 (1934) (remarks of FDA Chief Campbell regarding meaning of definitions); *Food, Drugs, and Cosmetics, 1934: Hearings on S. 2800 Before the Senate Comm. on Commerce*, 73d Cong. 516-518 (1934) (same); *Food, Drugs, and Cosmetics, 1935: Hearing on H.R. 6906, H.R. 8805, H.R. 8941 and S. 5 Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 74th Cong. 55-56 (1935) (same).

health claims on behalf of the manufacturer or vendor.” *FDA/DOJ Brief* at 16, 22 n.19. This history demonstrates that FDA’s prior position “that cigarettes are beyond the scope of the [FDCA] absent health claims” “accords with congressional intent in drafting the statute.” *Id.* at 14-15.

As the Justice Department explained:

[C]orrespondence dating from at least as early as 1940, show that [FDA’s] interpretation was in accordance with the *contemporaneous construction* of the 1938 Act by the persons charged with its administration.

Id. at 22, n.19 (emphasis added). “This contemporaneous administrative construction of the act is persuasive of the original” congressional “understanding, especially in light of the extensive role the [agency] played in drafting the statute and explaining its operation to Congress.” *Howe v. Smith*, 435 U.S. 110, 131 (1981); see also *United States v. American Trucking Ass’ns*, 310 U.S. 534, 549 (1940).

B. In the 1960s, Congress Rejected the Option of Granting FDA Authority to Regulate Tobacco Products, and Instead Enacted Its Own Regulatory Program that Provided No Role for FDA.

Congress addressed the possible health implications of tobacco products in the 1960s. Indeed, Congress was aware of the same concerns now raised by FDA to justify its assertion of jurisdiction: youth access, tobacco advertising, and the pharmacological effects of nicotine, e.g., “addiction.”⁹ In response to such concerns, Mem-

⁹ See, e.g., 109 Cong. Rec. 7,455 (1963) (Rep. Udall expressing concern over reports by “leading medical authorities” of the “harmful, and in fact deadly, effects of cigarette smoking” and “the increasing tempo of advertising in all media designed to lure young people into the use of cigarettes”); 108 Cong. Rec. 10,053 (1962)

bers of Congress again expressed interest in federal regulation of tobacco products, and introduced bills to amend the FDCA to grant FDA jurisdiction over cigarettes.¹⁰ These bills were introduced precisely because it was clear that "smoking products do not come under the protection of the FDA." 109 Cong. Rec. 10,318 (1963) (Sen. Moss). Again, however, Congress did not give FDA jurisdiction over tobacco products.

At the same time, FDA repeated its position that it could not regulate tobacco products unless they were sold with therapeutic claims. In 1963, FDA referred to "the exclusion of tobacco products from FDA's jurisdiction," and stated that: "tobacco marketed for chewing or smoking without accompanying therapeutic claims, does not meet the definitions in the [FDCA] for food, drug, device or cosmetic." Letter from FDA Bureau of Enforcement to Directors of Bureaus, Divisions and Directors of Districts (May 24, 1963) in *Public Health Cigarette Amendments of 1971: Hearings on S. 1454 Before the Consumer Subcomm. of the Senate Comm. on Commerce*, 92nd Cong. 240 (1972).

In 1964, the Advisory Committee to the Surgeon General on Smoking and Health issued its landmark "Report on Smoking and Health." U.S. Dep't of Health, Education and Welfare, Public Health Service, *Smoking and Health, Report of the Advisory Committee to the Surgeon General of the Public Health Service* (1964) ("1964

(Senator Neuberger noting statement of American Cancer Society official that "smoking is 'truly and in all respects an addiction,'" and that "help is needed to 'prevent new recruitment to smoking among the young'").

¹⁰ S. 1682, 88th Cong. (1963); H.R. 5973, 88th Cong. (1963); H.R. 9512, 88th Cong. (1963). Even prior to the 1960s, bills had been introduced to amend the FDCA to grant FDA authority over cigarettes. H.R. 11280, 84th Cong. (1956); S. 2554, 85th Cong. (1957); H.R. 592, 85th Cong. (1957). None of these bills were enacted.

Surgeon General Report"). The publicity was enormous, and Congress' response was swift. Legislation to permit FDA to regulate tobacco products was proposed, but Congress instead chose an entirely different course—it enacted the Federal Cigarette Labeling and Advertising Act ("FCLAA").

Hearings on the FCLAA commenced in 1964, shortly after the release of the Surgeon General's Report. Chairman Harris of the House Committee on Interstate and Foreign Commerce announced:

The purpose of these hearings will be . . . to determine the extent of authority under existing law to deal with [the issue of tobacco and health,] and to determine whether any action of the Congress is warranted in the interest of public health.

Cigarette Labeling and Advertising: Hearings Before the House Comm. on Interstate and Foreign Commerce, 88th Cong. 23 (1964) ("1964 Hearings").¹¹ When asked whether the Department of Health, Education and Welfare ("HEW") (FDA's parent) "presently has authority to brand or label the packages of cigarettes or to control the advertising," Surgeon General Terry responded without qualification: "we do not have such authority in existing laws governing the Public Health Service and Food and Drug Administration." *Id.* at 56.

¹¹ There "was no question at the time of the 1964 [Surgeon General's] Report that nicotine was the critical pharmacologic agent for tobacco." U.S. Dep't of Health and Human Services, Public Health Service, *The Health Consequences of Smoking: Nicotine Addiction, A Report of the Surgeon General*, 10 (1988); 1964 Surgeon General Report, at 69-75 (discussing scientific research regarding pharmacological effects of nicotine, including "stimulation," "tranquilization" and "suppression of appetite").

Congress specifically considered youth smoking and advertising: "[S]ome 4,500 boys and girls between the ages of 12 and 17 take up the habit each day of the year." 1964 Hearings at 34; see also *id.* at 16-17, 25-26, 31, 293-94.

Even those Members who believed that FDA should address smoking and health understood that the existing FDCA did not give FDA such authority. Instead, they introduced legislation to *grant* it such authority. *See id.* at 4-7.

However, HEW Secretary Celebrezze opposed those bills on the ground that FDA jurisdiction over cigarettes would likely result in their ban:

In light of the Advisory Committee's report on smoking and health, this provision might well completely outlaw at least cigarettes. This would be contrary to what, we understand, is intended or what, in the light of our experience with the 18th Amendment, would be acceptable to the American people.

Id. at 18. When Chairman Harris later observed that the one remaining bill to give FDA jurisdiction would lead to a tobacco ban, Rep. Udall, its sponsor, said he did not intend that result, and abandoned his bill. *Cigarette Labeling and Advertising—1965: Hearing on H.R. 2248 Before the House Comm. on Interstate and Foreign Commerce, 89th Cong. 29 (1965) ("1965 Hearings")*.

Shortly thereafter, FDA again testified that it "has no jurisdiction under the [FDCA] over tobacco, unless it bears drug claims." *Id.* at 193 (statement of FDA Deputy Comm'r Rankin). Although another bill was introduced to give FDA jurisdiction over cigarettes, H.R. 2248, 89th Cong. (1965), it did not pass. Thus, as it debated how best to respond to the Surgeon General's Report, Congress actively considered—then squarely rejected—any FDA involvement.

Instead, Congress enacted the FCLAA and made clear that it was retaining for itself sole authority to balance the important competing societal interests and to determine the appropriate federal regulation of cigarettes:

The determination of appropriate remedial action in this area . . . is a responsibility which should be exer-

cised by the Congress after considering all facets of the problem. The problem has broad implications in the field of public health and health research, and involves potentially far-reaching consequences for a number of sectors of our economy.

H.R. Rep. No. 89-449, 3 (1965) (emphasis added). Indeed, Congress took the step of announcing *in the statutory text* its overriding policy and purpose

to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby . . . the public may be adequately informed that cigarette smoking may be hazardous to health by inclusion of a warning to that effect . . . and . . . commerce and the national economy may be . . . protected to the maximum extent consistent with this declared policy

Pub. L. No. 88-92, § 2, 79 Stat. 282 (1965), *codified at* 15 U.S.C. § 1331 (emphasis added).

Congress' intent to withhold jurisdiction from FDA is further confirmed by the outcome of a broader debate over whether *any* administrative agency should be given any policymaking authority over smoking and health. Arguing for administrative flexibility, the FTC Chairman, the HEW Secretary, and the Surgeon General presented options for delegating new regulatory authority over tobacco to federal agencies. *1965 Hearings* at 38, 78-79. Several Members and witnesses expressed support for that view; others were opposed. *See e.g., id.* at 168-70, 240, 445-46; *Cigarette Labeling and Advertising: Hearings Before the Senate Commerce Comm. on S. 559 and S. 547, 89th Cong. at 405, 636, 692 (1965); 110 Cong. Rec. 15000-01 (1964)*.

As Rep. Rogers of Texas, author of the bill that passed the House, 111 Cong. Rec. 13900 (1965), and a Conference Committee member, *id.* at 13913, put the issue:

[T]he main issue here is who is going to put the reins on the situation involving an industry that is very important in this country at the present time from an economic standpoint, if reins are needed.

* * * *

[M]y bill was introduced for the purpose of laying down a situation that the Congress of this country, made up of the duly elected representatives under the Constitution, are still the ones who are supposed to set policy in this field.

1965 Hearings at 218.

Chairman Harris, manager of the FCLAA in the House, also addressed the "who" question: "I think it is a job for the Congress to do and not an executive agency or a regulatory agency through its own action. . . ." 111 Cong. Rec. 13900 (1965).

Sen. Hartke observed that "much of the time during the hearings" was devoted to considering whether the FTC

or any other federal administrative agency created by Congress should be permitted, [by] expanding authority delegated to it by Congress . . . to usurp the authority of the Congress in an area of national importance.

111 Cong. Rec. 13431 (1965) (emphasis added).

The FCLAA thus reflects Congress' decision to reserve to itself the decision-making responsibility for setting national policy respecting tobacco and health. Exclusion of FDA from regulation of cigarettes was indispensable to Congress' program because, as HEW Secretary Celebrezze had told Congress in 1964, FDA jurisdiction probably would lead to a ban. Given that understanding, the FCLAA "clearly bar[s] any expansion," *Northwest Bank Worthington v. Ahlers*, 485 U.S. 197, 206 (1988), of the FDCA to encompass tobacco products.

The policy established in the FCLAA—that cigarettes may be advertised and sold to adults but that smokers

must be informed of possible health hazards through warnings drafted by Congress—reflects Congress' balancing of health, consumer liberty, and "commerce and the national economy." FDA's assertion of jurisdiction—which under the FDCA would lead to a ban—would nullify that statutory scheme. Apart from a ban, FDA's authority over product labeling under the FDCA is inconsistent with the FCLAA labeling provisions. *Cf. Int'l Bhd. of Teamsters v. Daniel*, 439 U.S. 551, 567-70 (1979) (enactment of ERISA confirms SEC's lack of authority to reverse its prior understanding and expand its jurisdiction).

C. During the 1970s, FDA Reaffirmed that It Lacked Authority to Regulate Tobacco Products, and Congress Continued to Develop Its Own Regulatory Program, and to Exclude Agency Policymaking, on Tobacco and Health.

In 1969, Congress revisited the FCLAA and again focused on the issues of youth access, tobacco advertising, and "addiction." For example, one Member advised his colleagues, "The statistics indicate that 4,000 children every day are newly hooked on smoking." *Cigarette Labeling and Advertising—1969 (Part 1): Hearings on H.R. 643, H.R. 1237, H.R. 3055, H.R. 6543 Before the House Comm. on Interstate and Foreign Commerce, 91st Cong. 47 (1969) ("1969 Hearings")*. John Banzhaf, a founder of Action on Smoking and Health ("ASH"), testified that there was "substantial medical evidence" that "smoking to many people can be as addicting in the physical and medical sense as heroin" *Id.* at 288.

Congress responded by amending the FCLAA to prohibit broadcast advertisements for tobacco products and by strengthening the warning on cigarette packs. Pub. L. No. 91-222, § 6, 84 Stat. 87, 89 (1970).¹² Congress also

¹² The legislative history of the 1970 Amendments contains numerous comments on the need to discourage underage smoking and

reaffirmed that federal tobacco policy was a matter for Congress—not administrative agencies. The House Report states:

The regulations [proposed by the FTC and FCC would] . . . cut across the whole spectrum of commercial and social life in the United States. It is therefore an area where the Congress, if anyone, must make policy.

* * * *

Therefore, the committee feels that it is incumbent on the Congress to act on the reported legislation in order to prevent [administrative] intrusion . . . into basic areas of policymaking *which it has reserved to itself.*"

H.R. Rep. No. 91-289, 5 (1969) (emphasis added). Thus, Congress disparaged the "assumption by these agencies of policymaking with respect to a subject matter on which Congress has made policy [and] has stated its intention to be the exclusive policymaker." *Id.*

Two years later, FDA again advised Congress that it had no jurisdiction over tobacco products under the FDCA and that such jurisdiction would necessitate a ban:

[C]igarettes recommended for smoking pleasure are beyond the [FDCA]. . . . Indeed, if cigarettes were to be classified as drugs, they would have to be removed from the market because it would be impossible to prove they were safe for their intended use. . . .

cigarette advertising that appealed to youth. See 1969 Hearings 91st Cong. at 44-47, 54, 57, 69, 72-88, 169-70, 193, 224, 229, 263-64, 279, 286-89, 298-302, 314, 356, 273, 381, 430, 447, 451, 467, 471, 476, 484-90, 494, 497, 501-02, 601, 615-18, 625-35, 644-45, 679, 728-29, 737-38, 1201, 1287-88, 1291, 1303-07, 1340-41, 1350, 1371-72, 1376 (1969); *Cigarette Advertising and Labeling: Hearings on H.R. 8543 Before the Consumer Subcomm. of the Senate Comm. on Commerce*, 91st Cong., 33, 47-48, 76-79, 84-87, 98-99, 117, 121-22, 135, 156, 181 (1969).

[W]e believe [the FCLAA] demonstrates that *the regulation of cigarettes is to be the domain of Congress*. . . . In sum, labeling or banning cigarettes is a step that can be take[n] only by the Congress. Any such move by FDA would be inconsistent with the clear congressional intent.

Public Health Cigarette Amendments of 1971: Hearings on S. 1454 Before Consumer Subcomm. of the Senate Comm. on Commerce, 92nd Cong. 246 (1972) (emphasis added) (Statement of FDA Comm'r Edwards). FDA further acknowledged that Congress decided in the FCLAA

that cigarettes should not be banned, that they should be allowed to remain in commerce with the warnings decided on by Congress [and] we have no basis for making any kind of determination *literally contrary to the congressional determination*.

Id. at 245 (Statement of FDA Chief Counsel Hutt). Shortly thereafter, the FDA Chief Counsel, after consultation with the General Counsel of HEW, stated that "a test case [asserting FDA jurisdiction over cigarettes] would be without sound legal basis, and thus should not be instituted." *Id.* at 242 (letter from Chief Counsel Hutt to Sen. Moss).

By the early 1970s, Congress had established, and FDA had acknowledged, two fundamental propositions: First, Congress itself would regulate the health aspects of tobacco products through specific legislation that balanced health concerns with other factors, including the freedom of adults to smoke and the importance of tobacco to the national economy. Second, FDA would have no role in regulating tobacco products. Indeed, FDA's testimony reflects its understanding that, through the FCLAA, Congress had reserved such authority to itself. Thus, FDA's current assertion of jurisdiction over tobacco products

defies Congress' intent that no federal agency shall have authority to fashion federal tobacco and health policy.

Congress' intent to exclude administrative competition in the development of federal tobacco and health policy is expressed not only in the FCLAA; it is also manifest in post-FCLAA product safety statutes that expressly exclude tobacco products.¹³ FDA, of course, had made it clear that it could not regulate tobacco products. However, the same assurance could not be provided for a new agency, the Consumer Product Safety Commission ("CPSC"), which Congress created in 1972, pursuant to the Consumer Product Safety Act ("CPSA"), Pub. L. No. 92-573, 86 Stat. 1207 (1972) *codified at* 15 U.S.C. § 2051 *et seq.* So, Congress expressly excluded "tobacco products" from the CPSC's jurisdiction. *Id.* at § 2052(a)(1)(B).¹⁴

In 1976, Congress twice again precluded the possibility of agency interference with Congress' regulation of tobacco products. The CPSC had been ordered by a U.S.

¹³ The Government asserts that the FDCA's failure to expressly exclude tobacco products indicates that Congress never intended to bar FDA from regulating them. Pet. Br. at 19. To the contrary, FDA's repeated testimony to Congress that it lacked authority over tobacco products fully explains why, during this period, Congress did not have to consider amending the FDCA to explicitly exempt tobacco products. The Government's attempt to make affirmative use of the statutes that preclude administrative regulation of tobacco products ignores the unmistakable congressional policy which they embody—that no federal agency may regulate tobacco product health and safety absent specific congressional direction.

¹⁴ The CPSA was the product of competing bills. The House version that prevailed transferred from FDA to the CPSC responsibility over the Federal Hazardous Substances Act, *codified at* 15 U.S.C. § 1261 *et seq.*—which, among other things, provides that a hazardous substance may be banned. 15 U.S.C. § 2052(a)(1)(B). The Senate bill would have created a super product-safety agency built around FDA and the statutes for which it was then responsible—the FDCA and the FHSA. See S. Rep. 92-749, 12 (1972).

district court to consider the merits of a petition to ban high-tar cigarettes pursuant to the Federal Hazardous Substances Act ("FHSA"). Before the CPSC acted, Congress amended the FHSA to add an exclusion for tobacco products similar to the one it had adopted in the CPSA four years earlier. FDA understood the message that Congress intended to send, for it later interpreted the exclusion of tobacco products from FHSA as "indicative of the policy of Congress to limit regulatory authority over cigarettes by Federal Agencies." Novitch Letter, Jt. App. at 59.

A few months later, agency jurisdiction over tobacco arose again during Congress' consideration of the Toxic Substances Control Act ("TSCA"), Pub. L. No. 94-469, Title I, § 2, 90 Stat. 2003 (1976), *codified at* 15 U.S.C. § 2601 *et seq.*, which empowers the EPA to regulate and, if appropriate, to ban toxic chemical substances. Uncertain about how the EPA might apply this new authority, Congress excluded "tobacco or any tobacco product" from the TSCA. 15 U.S.C. § 2602(2)(B)(iii).

The import of these actions by Congress is unmistakable: After making FDA's confirmation that the FDCA could not apply to tobacco products a predicate of its own program in the FCLAA, Congress took the additional steps necessary to assure that no other federal agency could usurp Congress' control of federal tobacco and health policy.¹⁵

The statutory landscape was thus settled by 1976 when Congress passed the Medical Device Amendments to the

¹⁵ The public health acts passed by Congress in the 1970s also demonstrate Congress' continued understanding that tobacco products are separate from those products regulated under the FDCA. See 15 U.S.C. § 1261 (separately excluding "tobacco and tobacco products" and food, drugs, devices, and cosmetics from the FHSA); *id.* at § 2052 (separately excluding same product categories from the CPSA); *id.* at § 2602(2)(B) (separately excluding same product categories from the TSCA).

FDCA, Pub. L. No. 94-295, 90 Stat. 539 (1976). Nothing in the text, structure, or history of these amendments even hints that the same Congress that had precluded EPA and the CPSC from regulating tobacco products intended to give FDA the tools to do so. FDA itself stated:

[T]here is no evidence in the legislative history . . . that Congress intended to include cigarettes within the definition of "device" nor does the legislative history contain any discussion of a possibility that cigarettes were "devices" within the prior definition.

The amendments were thoroughly considered, and the legislative history discusses the types of products intended to be regulated and the types of health hazards with respect to which the amendments were intended to provide authority. Cigarettes are not mentioned even though Congress was aware of the considerable public discussion of the health hazards of cigarette smoking.

Novitch Letter, Jt. App. at 54 (emphasis added). Only a year later, FDA again declared that it had "*no authority to regulate*" cigarettes. 42 Fed. Reg. 19,996, 20,001 (1977) (emphasis added).

In May 1977, ASH petitioned FDA to regulate cigarettes as "drugs" on the ground that they contain nicotine, which ASH contended produces a "physical addiction" in many smokers, including young smokers. *Citizen Petition*, FDA Dkt. No. 77P-0185 at 4-11 (May 26, 1977). This was the same argument ASH had presented to Congress in 1969 prior to its amending the FCLAA—and that FDA now invokes to justify its assertion of jurisdiction.

In fact, most of the arguments FDA now advances as "new" grounds for asserting jurisdiction over cigarettes, *see* 61 Fed. Reg. 44,396, 45,226 (1996), were presented to FDA in ASH's 1977 petition, just as they had been presented to Congress in the 1960s:

- the nicotine in cigarettes is a drug (p. 2);
- "studies have demonstrated that many smokers smoke largely for the physiological effects the drug causes on their body" (p. 2);
- "[n]umerous medical and other studies treat nicotine as a drug no different in many of its effects than heroin and other addictive substances" (p. 2);
- "overwhelming persuasive evidence" shows that "cigarettes are 'intended to affect the functions of the body' by many users as well as by the manufacturers" (p. 2);
- "[n]icotine is an extremely powerful substance exerting powerful effects . . . on the brain, spinal cord, peripheral nervous system, the heart, lungs and various other bodily structures" (p. 6);
- "[s]tudies going back at least to 1940 . . . indicate that for many smokers the act of smoking is merely a convenient and socially accepted manner of administering a carefully-controlled dose of nicotine to the body" (pp. 7-8);
- a "cigarette, is after all, an instrument, apparatus, or contrivance *designed* to administer controlled amounts of nicotine and other substances to the smoker upon demand" (p. 31) (emphasis added); and
- "most children have no trouble acquiring the product" (p. 36).

In rejecting the ASH petition, FDA did not dispute any of ASH's factual assertions. Instead, it rejected the petition *as a matter of law* on the ground that such allegations, *even if true*, could not authorize FDA to regulate cigarettes. FDA confirmed that its "interpretation of the [FDCA] . . . consistently has been that cigarettes are not a drug unless health claims are made by the vendors." Letter from FDA Comm'r Kennedy to Banzhaf, Jt. App. at 47 (Dec. 5, 1977) (emphasis added). Accord-

ing to FDA, "citations in the petition that cigarettes are used by smokers to affect the structure or any functions of their bodies *are not evidence* of such intent by the manufacturers or vendors of cigarettes . . ." *Id.*, Jt. App. at 48-49 (citation omitted) (emphasis added).

When ASH challenged in court FDA's rejection of its petition that FDA regulate cigarettes as "contrivance[s] designed to administer controlled amounts of nicotine," *Citizen Petition* at 31, FDA and the Justice Department defended the Agency's determination that it lacked jurisdiction over cigarettes:

In the 73 years since the enactment of the original Food and Drug Act, and in the 41 years since the promulgation of the modern Food, Drug, and Cosmetic Act, the FDA has repeatedly informed Congress that cigarettes are beyond the scope of the statute absent health claims establishing a therapeutic intent on behalf of the manufacturer or vendor.

FDA/DOJ Brief at 14-15. Although "the hazards of smoking, including its addictive effects, were known in 1952," *id.* at 29, n.24, FDA and the Justice Department stated:

Since at least the issuance of the Surgeon General's Report on smoking in 1964, cigarettes have been at the forefront of discussions of the public health—in Congress, in the Executive Branch, in the news media, and among the public generally. *The participants in these discussions over the past 15 [now 35] years or more would be shocked to learn that during all this time FDA has had jurisdiction to regulate cigarettes as drugs, and presumably to ban them.*

Id. at 40 (emphasis added).

As FDA and the Justice Department recognized, any change in such a longstanding interpretation would be contrary to clear congressional intent:

Although it has amended the Act many times, Congress has never acted to disturb the agency's interpretation. In such circumstances, the Supreme Court has recognized Congressional acquiescence in the FDA's construction of the Act.

Id. at 27 n.23 (citation omitted).

These arguments prevailed. *See ASH*, 655 F.2d at 236. The court of appeals expressly endorsed the statutory interpretation that the pharmacological effects of nicotine do *not* provide a basis for FDA jurisdiction. *Id.* at 240.

In 1978, ASH again petitioned FDA, this time arguing that filtered cigarettes are intended to mitigate or prevent disease and thus were medical "devices" under the FDCA. *Citizen Petition*, Dkt. No. 78P-0338 (Oct. 2, 1978). However, FDA concluded that it is

not reasonable to consider cigarettes as "devices" when there was no discussion in the legislative history of congressional intent to provide jurisdiction over cigarettes or to provide authority suitable to the regulation of cigarettes.

Novitch Letter, Jt. App. at 54. Thus, "[i]nsofar as rule-making would relate to cigarettes . . . as customarily marketed, . . . FDA has no jurisdiction [and] no rule-making is permissible as a matter of law." *Id.* at 67 (emphasis added). FDA recognized that its lack of jurisdiction was inherent in the FDCA and not due to a lack of evidence or an exercise of administrative discretion.¹⁶

¹⁶ While the ASH petitions were before the Agency, five bills were introduced to grant FDA jurisdiction over cigarettes. H.R. 2419, 95th Cong. (1977); H.R. 3879, 95th Cong. (1977); H.R. 7168, 95th Cong. (1977); S. 3317, 95th Cong. (1978); H.R. 279, 96th Cong. (1979). None was enacted.

D. During the 1980s and 1990s, Congress Supplemented Its Regulatory Program for Tobacco Products in Ways Squarely Inconsistent with FDA Jurisdiction.

Congress has continued to refine its program for tobacco regulation through legislation *specifically* addressing aspects of a product that even FDA has recognized raises "unique" issues. 61 Fed. Reg. 44,396, 44,404 (1996).

In 1983, Congress required the Secretary of HHS to report to Congress every three years on the "addictive property of tobacco," and to include recommendations for action that the Secretary may deem appropriate. Alcohol and Drug Abuse Amendments of 1983, Pub. L. No. 98-24, §2(b)(7), 97 Stat. 175, 178 (1983), *codified at* 42 U.S.C. § 290aa *et seq.*

The next year, Congress again amended the FCLAA to modify the prescribed warning for cigarettes, reaffirming that the FTC—not FDA—would continue to administer this requirement. *See Comprehensive Smoking Education Act of 1984*, Pub. L. No. 98-474, 98 Stat. 2200 (1984), *amending* 15 U.S.C. § 1331 *et seq.* In the opening hearing, Chairman Waxman of the House Subcommittee on Health and the Environment, a proponent of increased tobacco regulation, remarked:

The [FDA] is charged with assuring that the public is adequately warned about the health effects of drugs and that hazardous foods and drugs are removed from the market. *Yet, no Federal agency has jurisdiction over cigarettes. . . . The responsibility to regulate the cigarette industry falls to the Congress.*

Smoking Prevention Education Act: Hearings on H.R. 1824 Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 98th Cong. 1 (1983) (emphasis added).

Assistant Secretary for Health Brandt, speaking on behalf of FDA, agreed: "[T]he issue of regulation of tobacco . . . is *something that Congress has reserved to itself*, and we do not . . . have the authority to regulate nor are we seeking such authority." *Id.* at 74 (emphasis added). Dr. Brandt repeated this understanding to the Senate: "Our view is that the Congress has assumed the responsibility of regulating . . . cigarettes." *Smoking Prevention Health and Education Act of 1983: Hearings on S. 772 Before the Comm. on Labor and Human Resources*, 98th Cong. 56 (1983).

The House committee with jurisdiction over FDA agreed: "Federal laws that protect the public from hazardous food, drugs and consumer products do not apply to cigarettes" H.R. Rep. No. 98-805, 12 (1984).

As part of these FCLAA amendments, Congress also required cigarette manufacturers to "annually provide the Secretary [of HHS] with a list of the ingredients added to tobacco in the manufacture of cigarettes" 15 U.S.C. § 1335a(a). This section—which authorizes the Secretary to report directly to Congress on the health effects of those ingredients—reflected Congress' concern that

[a]t the present time, cigarette manufacturers are not statutorily required to disclose to any agency or department of the federal government any of the ingredients they place in cigarettes during the manufacturing process.

H.R. Rep. No. 98-805, 21 (1984). This statement shows that FDA lacks jurisdiction over tobacco products.

In 1986, Congress enlarged its national tobacco program when it passed the Comprehensive Smokeless Tobacco Health Education Act ("CSTHEA"), Pub. L. No. 99-252, 100 Stat. 30 (1986), *codified at* 15 U.S.C. § 4401 *et seq.*, relying in part on the fact that "FDA claims [that]

it does not have the authority to regulate the sale of smokeless tobacco." *Tobacco Issues: Hearings on H.R. 2835, H.R. 760, H.R. 2950, and H.R. 3078, Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 99th Cong. 106 (1985) (statement of Rep. Synar). The CSTHEA bans broadcast advertising of smokeless tobacco products, establishes a mandatory warning format, and authorizes the FTC—not FDA—to issue implementing regulations. 15 U.S.C. §§ 4401-08. The CSTHEA thus rests on the same fundamental policy embodied in the FCLAA—that informed adults should be permitted to decide whether or not to use tobacco products.¹⁷

In 1988, the Surgeon General declared that nicotine is "addictive". U.S. Dep't of Health and Human Services, Public Health Service, *The Health Consequences of Smoking: Nicotine Addiction, A Report of the Surgeon General* (1988); see also U.S. Dep't of Health and Human Services, Public Health Service, *Reducing the Health Consequences of Smoking: 25 Years of Progress, A Report of the Surgeon General*, 10 (1989) ("1989 Surgeon General Report").

Rep. Durbin brought the "addiction" issue to the attention of the House:

Congress declares war on addictive drugs, yet we virtually ignore one of the greatest causes of addiction in America: Tobacco. We regulate food and drugs to protect the health of our citizens, but we specifically exempt the cause of 350,000 American deaths each year: Tobacco. . . . *The Congress should change the Food, Drug and Cosmetic Act to define nicotine as a drug. That would make all*

¹⁷ In 1987, Congress failed to enact yet another bill that would have expanded FDA jurisdiction to cover tobacco products. See H.R. 3294, 100th Cong. (1987).

tobacco products subject to regulation by the FDA, allowing us to restrict sales to children

134 Cong. Rec. 11,261 (1988) (emphasis added).¹⁸

The next year, two bills were introduced in both Houses to amend the FDCA to give FDA jurisdiction over tobacco products. See H.R. 1494, 101st Cong. (1989); S. 769, 101st Cong. (1989). Again, Congress did not enact either of them even though their proponents argued that the issues of youth smoking and "addiction"—the same issues that FDA itself now advances—called for expanded FDA jurisdiction:

[E]very day, more than 3,000 American teenagers—or 60 percent of all new smokers—start smoking. Yet . . . tobacco products are largely exempted from the laws we have established to protect the public from unsafe consumer products. All of this despite that fact that we now know without question that cigarettes and other tobacco products containing nicotine are highly addictive.

135 Cong. Rec. 6,550 (1989) (statement of Rep. Durbin).

Even after the Surgeon General reported in 1988 that nicotine in tobacco products is addictive, FDA Commis-

¹⁸ Respondents' history of Congress' consideration of tobacco product legislation between 1964 and 1988 is consistent with that of the Surgeon General:

Following the 1964 Surgeon General's Report, Congress considered a number of bills to regulate tobacco [including] amending the FFDCFA to place cigarettes under the authority of the FDA. Because there was no known safe level for tar, nicotine or other tobacco constituents, regulation would have likely resulted in prohibition. . . . Instead, following considerable debate [Congress enacted the FCLAA]

1989 Surgeon General Report at 605, 612-613 (noting further that, rather than "allowing regulation by Federal agencies, Congress in most cases reserved to itself jurisdiction over tobacco products. . . .").

sioner Young testified that "it doesn't look like it is possible to regulate [tobacco] under the [FDCA] even though smoking, I think, has been widely recognized as being harmful to human health." *Rural Development, Agriculture, and Related Agencies Appropriations for 1989: Hearings Before a Subcomm. of the House Comm. on Appropriations*, 100th Cong. 409 (1989). Rep. Durbin agreed: "I think the legal interpretation is fairly clear that tobacco is not included in your legislative mandate." *Id.*

Commissioner Young's reaffirmation of FDA's long-held view that it does not have jurisdiction over cigarettes prompted some Members of Congress to call for new statutory restrictions on cigarette advertising. In 1990, for example, Rep. Waxman sponsored a bill that would have made it a federal offense to distribute free tobacco-product samples, sponsor sporting events using cigarette brand names, or advertise in anything other than a black-and-white format. *See* H.R. 5041, 101st Cong. (1990). The House Commerce Committee did not report the proposed legislation, yet these same unenacted restrictions are now found in FDA's current regulations. *See* 21 C.F.R. §§ 897.16(d), 897.34(c), 897.32.¹⁹

In response to such concerns about youth and tobacco, Congress expanded its tobacco program in 1992 by enacting the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992 ("ADAMHA Amendments"). Pub. L. No. 102-321, Title II, § 202, 106 Stat. 394, *codified at* 42 U.S.C. § 300x-26. Through these Amendments, Congress determined that the States—not the federal government—should remain responsible for re-

¹⁹ These restrictions were rejected by the same Congress that enacted the Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511-30 (1990), which FDA claims supports its authority to impose some of the same restrictions in the guise of regulating tobacco products as "devices."

stricting underage access to tobacco products: The federal government creates incentives for the States to pursue their traditional role of regulating the retail sale of tobacco products by withholding funds from States that fail to enact or adequately enforce their own laws prohibiting tobacco product sales to minors.²⁰

In the ADAMHA Amendments, Congress sought to preserve State flexibility and declined to "force a particular standard upon all states," 58 Fed. Reg. 45,156, 45,161 (1993) (proposed implementing regulations).

[E]ach State should have the flexibility to enforce its laws in a manner that can reasonably be expected to reduce availability of tobacco products to minors in light of that State's own unique circumstances.

61 Fed. Reg. 1492, 1495. (1996). Yet, soon after the ADAMHA regulations were finalized, FDA seized jurisdiction and announced its own uniform national tobacco-access requirements, thereby supplanting Congress' program.

E. Following the 1994 Elections, FDA Abruptly Decided to Regulate Tobacco Products Without Congressional Authorization.

In 1994, FDA announced that it would "work with Congress" to consider whether the Agency could assert jurisdiction over cigarettes as "drugs." FDA expressly recognized that it was "vital" that "Congress provide clear direction to the agency" because "the regulation of cigarettes raises societal issues of great complexity and mag-

²⁰ In 1992, legislation was also introduced—H.R. 4350 and S. 2298, 102d Cong. (1992)—to expand FDA jurisdiction by creating a new regulatory category for tobacco products. Rep. Synar observed that FDA "is powerless to do anything" about tobacco products. 138 Cong. Rec. 4028-29 (1992). Again, in 1993, two more bills were introduced that would have expanded FDA jurisdiction to include tobacco products. H.R. 2147 and S. 672, 103d Cong. (1993). None of these bills passed.

nitide." Letter from FDA Comm'r Kessler to Ballin (Feb. 25, 1994), in *Regulation of Tobacco Products (Part I), Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 103rd Cong. 3, 25 (1994) ("1994 Hearings"). See also 1994 Hearings at 73 (statement of Comm'r Kessler seeking "guidance from the Congress").

FDA quickly lost interest in working with Congress following the November 1994 election that resulted in a change in the political control of Congress. One day after that election, the Agency announced that "FDA will make" the decision on its jurisdiction over tobacco products. Letter from FDA Assoc. Comm'r Thompson to Rep. Lancaster 2 (Nov. 10, 1994).²¹ Thereafter, without any direction—much less authorization—from Congress, FDA asserted jurisdiction over tobacco products.²² FDA Deputy Commissioner Shultz candidly described this decision as "historic" precisely "because it provided an opportunity for taking decisive action on tobacco without requiring action by Congress." Schultz, *The FDA's Decision to Regulate Tobacco Products*, 18 Pace L. Rev. 27, 29 (1997).

FDA's excuse for its abrupt about face is its contention that it has unearthed "new facts" showing that nicotine is an addictive drug.²³ Even if those "new facts" had legal

²¹ While FDA reconsidered asserting jurisdiction over tobacco products, Congress excluded them from the definition of "dietary supplement," which otherwise included any "botanical product," in the Dietary Supplement Health and Education Act ("DSHEA"), Pub. L. No. 103-417 § 3, 108 Stat. 4325, 4327 (1994). The exclusion was unnecessary, but it precluded FDA from using the DSHEA to reach tobacco products as dietary supplements.

²² Two months before FDA proposed its tobacco rule, a bill was introduced to give FDA new authority to regulate tobacco products. H.R. 1853, 104th Cong. (1995). The bill was not enacted.

²³ Under FDA's new interpretation of "drug," neither "addiction" nor any other particular pharmacological effect is necessary

relevance, which they do not, FDA's explanation does not withstand scrutiny. Pharmacological effects of nicotine have been well known for decades. Indeed, they were known in 1938 when Congress enacted the FDCA, were catalogued in the 1964 Surgeon General's Report, and were extensively discussed in the 1979 report by the National Institute of Drug Abuse which concluded that cigarettes are addictive. See notes 4 and 11, *supra*; National Institute on Drug Abuse, *The Behavioral Aspects of Smoking* (1979), reprinted in Dep't of Health, Education, and Welfare, Public Health Service, *Smoking and Health, A Report of the Surgeon General*, ch. 15 (1979). These facts are not new.²⁴ The only thing new is FDA's willingness to ignore statutory restraints.

F. Congress Continues to Address Smoking and Health Issues.

In the last Congress, legislation to grant FDA jurisdiction over tobacco products was considered on the

for FDA jurisdiction. Any kind of physical effect on the body would suffice, including the many kinds of adverse effects ascribed to tobacco products in the 1964 Surgeon General's Report.

²⁴ FDA acknowledged that the "long history of tobacco and nicotine use for pharmacological purposes" was "well known to the tobacco industry," an acknowledgement it based on a study published in 1965. 60 Fed. Reg. 41,314, 41,621 n.240 (1995). FDA also relied on many other published studies about the tobacco industry's knowledge of pharmacological effects of nicotine from the 1950s through the 1970s. See 61 Fed. Reg. 44,396, 44,895-912, 44,952-53 (1996). Given FDA's claim that foreseeability of pharmacological effects has always established the requisite intended use of a product to affect the structure or function of the body, Pet. Br. at 4, the basis for FDA's current theory of jurisdiction has existed for many decades.

The Government asserts that "basic drug-like qualities [of tobacco products] are so well documented, widely known and thoroughly embedded in the behavior of consumers and manufacturers," that express claims to that effect would be "superfluous." Pet. Br. at 25. Apparently, FDA's argument is that until 1995 everyone was aware of these facts except FDA.

arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: *Provided*, That to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided*, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: *Provided*, That the method of packing may be modified with the consent of the Secretary. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States, and not to those of the United States Pharmacopoeia.

(h) If it has been found by the Secretary to be a drug liable to deterioration, unless it is packaged in such form

and manner, and its label bears a statement of such precautions, as the Secretary shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Secretary shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i)(1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

EXEMPTIONS IN CASE OF DRUGS AND DEVICES

SEC. 503. (a) The Secretary is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

(b) A drug dispensed on a written prescription signed by a physician, dentist, or veterinarian (except a drug dispensed in the course of the conduct of a business of dispensing drug pursuant to diagnosis by mail), shall if—

(1) such physician, dentist, or veterinarian is licensed by law to administer such drug, and

(2) such drug bears a label containing the name and place of business of the dispenser, the serial number and date of such prescription, and the name of such physician, dentist, or veterinarian,

be exempt from the requirements of section 502 (b) and (e), and (in case such prescription is marked by the writer thereof as not refillable or its refilling is prohibited by law) of section 502 (d).

CERTIFICATION OF COAL-TAR COLORS FOR DRUGS

SEC. 504. The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in drugs for purposes of coloring only and for the certification of batches of such colors, with or without harmless diluents.

NEW DRUGS

SEC. 505. (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to subsection (b) is effective with respect to such drug.

(b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for,

the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug.

(c) An application provided for in subsection (b) shall become effective on the sixtieth day after the filing thereof unless prior to such day the Secretary by notice to the applicant in writing postpones the effective date of the application to such time (not more than one hundred and eighty days after the filing thereof) as the Secretary deems necessary to enable him to study and investigate the application.

(d) If the Secretary finds, after due notice to the applicant and giving him an opportunity for a hearing, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; or (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions, he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

(e) The effectiveness of an application with respect to any drug shall, after due notice and opportunity for hearing to the applicant, by order of the Secretary be suspended if the Secretary finds (1) that clinical experience, tests by new methods, or tests by methods not deemed reasonably applicable when such application became effective show that such drug is unsafe for use under the conditions of use upon the basis of which the application became effective, or (2) that the application contains any untrue statement of a material fact. The order shall state the findings upon which it is based.

(f) An order refusing to permit an application with respect to any drug to become effective shall be revoked whenever the Secretary finds that the facts so require.

(g) Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the department designated by the Secretary or (2) by mailing the order by registered mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

(h) An appeal may be taken by the applicant from an order of the Secretary refusing to permit the application to become effective, or suspending the effectiveness of the application. Such appeal shall be taken by filing in the district court of the United States within any district wherein such applicant resides or has his principal place of business, or in the District Court of the United States for the District of Columbia, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith served upon the Secretary, or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the record upon which the order complained

of was entered. Upon the filing of such transcript such court shall have exclusive jurisdiction to affirm or set aside such order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment and decree of the court affirming or setting aside any such order of the Secretary shall be final, subject to review as provided in sections 128, 239, and 240 of the Judicial Code, as amended (U. S. C., 1934 ed., title 28, secs. 225, 346, and 347), and in section 7, as amended, of the Act entitled "An Act to establish a Court of Appeals for the District of Columbia", approved February 9, 1893 (D. C. Code, title 18, sec. 26). The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

(i) The Secretary shall promulgate regulations for exempting from the operation of this section drugs intended

solely for investigational use by experts qualified by scientific training and experience to investigate the safety of drugs.

CHAPTER VI—COSMETICS

ADULTERATED COSMETICS

SEC. 601. A cosmetic shall be deemed to be adulterated—

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual: *Provided*, That this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.", and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(c) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(e) If it is not a hair dye and it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 604.

MISBRANDED COSMETICS

SEC. 602. A cosmetic shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If its container is so made, formed, or filled as to be misleading.

REGULATIONS MAKING EXEMPTIONS

SEC. 603. The Secretary shall promulgate regulations exempting from any labeling requirement of this Act cosmetics which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial

quantities at establishments ~~other~~ than those where originally processed or packed, on condition that such cosmetics are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

CERTIFICATION OF COAL-TAR COLORS FOR COSMETICS

SEC. 604. The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in cosmetics and for the certification of batches of such colors, with or without harmless diluents.

CHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

REGULATIONS AND HEARINGS

SEC. 701. (a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.

(b) The Secretary of the Treasury and the Secretary of Agriculture shall jointly prescribe regulations for the efficient enforcement of the provisions of section 801, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Agriculture shall determine.

(c) Hearings authorized or required by this Act shall be conducted by the Secretary or such officer or employee as he may designate for the purpose.

(d) The definitions and standards of identity promulgated in accordance with the provisions of this Act shall

be effective for the purposes of the enforcement of this Act, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

(e) The Secretary, on his own initiative or upon an application of any interested industry or substantial portion thereof stating reasonable grounds therefor, shall hold a public hearing upon a proposal to issue, amend, or repeal any regulation contemplated by any of the following sections of this Act: 401, 403 (j), 404 (a), 406 (a) and (b), 501 (b), 502 (d), 502 (h), 504, and 604. The Secretary shall give appropriate notice of the hearing, and the notice shall set forth the proposal in general terms and specify the time and place for a public hearing to be held thereon not less than thirty days after the date of the notice, except that the public hearing on regulations under section 404 (a) may be held within a reasonable time, to be fixed by the Secretary, after notice thereof. At the hearing any interested person may be heard in person or by his representative. As soon as practicable after completion of the hearing, the Secretary shall by order make public his action in issuing, amending, or repealing the regulation or determining not to take such action. The Secretary shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based. No such order shall take effect prior to the ninetieth day after it is issued, except that if the Secretary finds that emergency conditions exist necessitating an earlier effective date, then the Secretary shall specify in the order his findings as to such conditions and the order shall take effect at such earlier date as the Secretary shall specify therein to meet the emergency.

(f)(1) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. The summons and petition may be served at any place in the United States. The Secretary, promptly upon service of the summons and petition, shall certify and file in the court the transcript of the proceedings and the record on which the Secretary based his order.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) The court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action, with respect to such

regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 239 and 240 of the Judicial Code, as amended.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

(g) A certified copy of the transcript of the record and proceedings under subsection (e) shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, libel for condemnation, exclusion of imports, or other proceeding arising under or in respect to this Act, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f).

EXAMINATIONS AND INVESTIGATIONS

SEC. 702. (a) The Secretary is authorized to conduct examinations and investigations for the purposes of this Act through officers and employees of the Department or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department. In the case of food packed in a Territory the

Secretary shall attempt to make inspection of such food at the first point of entry within the United States when, in his opinion and with due regard to the enforcement of all the provisions of this Act, the facilities at his disposal will permit of such inspection. For the purposes of this subsection the term "United States" means the States and the District of Columbia.

(b) Where a sample of a food, drug, or cosmetic is collected for analysis under this Act the Secretary shall, upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent; except that the Secretary is authorized, by regulations, to make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this subsection as he finds necessary for the proper administration of the provisions of this Act.

(c) For purposes of enforcement of this Act, records of any department or independent establishment in the executive branch of the Government shall be open to inspection by any official of the Department of Agriculture duly authorized by the Secretary to make such inspection.

RECORDS OF INTERSTATE SHIPMENT

SEC. 703. For the purpose of enforcing the provisions of this Act, carriers engaged in interstate commerce, and persons receiving food, drugs, devices, or cosmetics in interstate commerce or holding such articles so received, shall, upon the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times, to have access to and to copy all records showing the movement in interstate commerce of any food, drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity,

shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, or cosmetic to which such request relates: *Provided*, That evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained: *Provided further*, That carriers shall not be subject to the other provisions of this Act by reason of their receipt, carriage, holding, or delivery of food, drugs, devices, or cosmetics in the usual course of business as carriers.

FACTORY INSPECTION

SEC. 704. For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, after first making request and obtaining permission of the owner, operator, or custodian thereof, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or are held after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.

PUBLICITY

SEC. 705. (a) The Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Act, including the nature of the charge and the disposition thereof.

(b) The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

COST OF CERTIFICATION OF COAL-TAR COLORS

SEC. 706. The admitting to listing and certification of coal-tar colors, in accordance with regulations prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

CHAPTER VIII—IMPORTS AND EXPORTS

SEC. 801. (a) The Secretary of the Treasury shall deliver to the Secretary of Agriculture, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Agriculture and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions, or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 505, then such article shall be refused admission. This paragraph shall not be construed to prohibit the admission of narcotic drugs the importation of which is permitted under section 2 of the Act of May 26, 1922, as amended (U.S.C., 1934 edition, title 21, sec. 173).

(b) The Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any such article refused admission, unless such article is exported by the consignee within three months from the date of notice of such refusal, under such regulations as the Secretary of the Treasury may prescribe: *Provided*, That the Secretary of the Treasury may deliver to the consignee any such article pending examination and decision in the matter on execution of a bond as liquidated damages for the amount of the full invoice value thereof together with the duty thereon and on refusing for any cause to return such article or any part thereof to the custody of the Secretary of the Treasury when demanded for the purpose of excluding it from the country or for any other purpose, such consignee shall forfeit the full amount of the bond as liquidated damages.

(c) All charges for storage, cartage, and labor on any article which is refused admission or delivery shall be paid by the owner or consignee and in default of such payment shall constitute a lien against any future importations made by such owner or consignee.

(d) A food, drug, device, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act if it (1) accords to the specifications of the foreign purchaser, (2) is not in conflict with the laws of the country to which it is intended for export, and (3) is labeled on the outside of the shipping package to show that it is intended for export. But if such article is sold or offered for sale in domestic commerce, this subsection shall not exempt it from any of the provisions of this Act.

CHAPTER IX—MISCELLANEOUS

SEPARABILITY CLAUSE

SEC. 901. If any provision of this Act is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the Act and the applicability thereof to other persons and circumstances shall not be affected thereby.

EFFECTIVE DATE AND REPEALS

SEC. 902. (a) This Act shall take effect twelve months after the date of its enactment. The Federal Food and Drugs Act of June 30, 1906, as amended (U. S. C., 1934 ed., title 21, secs. 1-15), shall remain in force until such effective date, and, except as otherwise provided in this subsection, is hereby repealed effective upon such date: *Provided*. That the provisions of section 701 shall become effective on the enactment of this Act, and thereafter the Secretary is authorized hereby to (1) conduct hearings and to promulgate regulations which shall become effective on or after the effective date of this Act as the Secretary shall direct, and (2) designate prior to the effective date of this Act food having common or usual names and exempt such food from the requirements of clause (2) of section 403 (i) for a reasonable time to permit the formulation, promulgation, and effective application of definitions and standards of identity therefor as provided by section 401: *Provided further*, That sections 502 (j), 505, and 601 (a), and all other provisions of this Act to the extent that they may relate to the enforcement of such sections, shall take effect on the date of the enactment of this Act, except that in the case of a cosmetic to which the proviso of section 601 (a) relates, such cosmetic shall not, prior to the ninetieth day after such date

of enactment, be deemed adulterated by reason of the failure of its label to bear the legend prescribed in such proviso: *Provided further*, That the Act of March 4, 1923 (U. S. C., 1934 ed., title 21, sec. 6; 42 Stat. 1500, ch. 268), defining butter and providing a standard therefor; the Act of July 24, 1919 (U. S. C., 1934 ed., title 21, sec. 10; 41 Stat. 271, ch. 26), defining wrapped meats as in package form; and the amendment to the Food and Drugs Act, section 10A, approved August 27, 1935 (U. S. C., 1934 ed., Sup. III, title 21, sec. 14a), shall remain in force and effect and be applicable to the provisions of this Act.

(b) Meats and meat food products shall be exempt from the provisions of this Act to the extent of the application or the extension thereto of the Meat Inspection Act, approved March 4, 1907, as amended (U. S. C., 1934 ed., title 21, secs. 71-91; 34 Stat. 1260 et seq.).

(c) Nothing contained in this Act shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the virus, serum, and toxin Act of July 1, 1902 (U. S. C., 1934 ed., title 42, chap. 4); the Filled Cheese Act of June 6, 1896 (U. S. C., 1934 ed., title 26, ch. 10), the Filled Milk Act of March 4, 1923 (U. S. C., 1934 ed., title 21, ch. 3, secs. 61-63); or the Import Milk Act of February 15, 1927 (U. S. C., 1934 ed., title 21, ch. 4, secs. 141-149).

(d) In order to carry out the provisions of this Act which take effect prior to the repeal of the Food and Drugs Act of June 30, 1906, as amended, appropriations available for the enforcement of such Act of June 30, 1906, are also authorized to be made available to carry out such provisions.

Approved, June 25, 1938.

21 U.S.C. § 321(p)(1) provides as follows:

§ 321. Definitions; generally

* * * *

(p) The term "new drug" means—

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to June 25, 1938, it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use

21 U.S.C. §§ 351(b) and (c) provides as follows:

§ 351. Adulterated drugs and devices

A drug or device shall be deemed adulterated—

* * * *

(b) Strength, quality, or purity differing from official compendium

If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary, shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay have not been prescribed in such compendium, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United

States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

(c) Misrepresentation of strength, etc., where drug is unrecognized in compendium

If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

21 U.S.C. § 352(e)(1) provides as follows:

§ 352. Misbranded drugs and devices

A drug or device shall be deemed to be misbranded—

* * * *

(e) Designation of drugs or devices by established names

(1)(A) If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula)—

(i) the established name (as defined in subparagraph (3)) of the drug, if there is such a name,

(ii) the established name and quantity, or if determined to be appropriate by the Secretary, the proportion of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not the established name and quantity or if determined by the Secretary, the proportion of any bromides, ether, chloroform, acetanilide, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein, except that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subclause, shall not apply to non-prescription drugs not intended for human use; and

(iii) the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package and, if determined to be appropriate by the Secretary, on the immediate container, as prescribed in regulation promulgated by the Secretary, ex-

cept that nothing in this subclause shall be deemed to require that any trade secret be divulged, and except that the requirements of this subclause with respect to alphabetical order shall apply only to nonprescription drugs that are not also cosmetics and that this subclause shall not apply to nonprescription drugs not intended for human use.

(B) For any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) shall be printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient, except that to the extent that compliance with the requirements of subclause (ii) or (iii) of clause (A) or this clause is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

21 U.S.C. § 353(b)(1) provides as follows:

§ 353. Exemptions and consideration for certain drugs, devices, and biological products

* * * *

(b) Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws

(1) A drug intended for use by man which—

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(B) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug;

shall be dispensed only (i) upon written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

21 U.S.C. § 360c(a)(1)-(2) provides as follows:

§ 360c. Classification of devices intended for human use

(a) Classes of devices

(1) There are established the following classes of devices intended for human use:

(A) CLASS I, GENERAL CONTROLS.—

(i) A device for which the controls authorized by or under section 351, 352, 360, 360f, 360h, 360i, or 360j of this title or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but because it—

(I) is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and

(II) does not present a potential unreasonable risk of illness or injury.

is to be regulated by the controls referred to in clause (i).

(B) CLASS II, SPECIAL CONTROLS.— A device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide

such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 360(k) of this title), recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance. For a device that is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.

(C) CLASS III, PREMARKET APPROVAL.— A device which because—

(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and

(ii) (I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or

(II) presents a potential unreasonable risk of illness or injury,

is to be subject, in accordance with section 360e of this title, to premarket approval to provide reasonable assurance of its safety and effectiveness.

If there is not sufficient information to establish a performance standard for a device to provide reasonable assurance of its safety and effectiveness, the Secretary may conduct such activities as may be necessary to develop or obtain such information.

(2) For purposes of this section and sections 360d and 360e of this title, the safety and effectiveness of a device are to be determined—

(A) with respect to the persons for whose use the device is represented or intended,

(B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and

(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

No. 98-1152

Supreme Court, U.S.

FILED

SEP 10 1999

THE CLERK

IN THE
Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, *et al.*,
Petitioners,

v.

BROWN AND WILLIAMSON TOBACCO CORP., *et al.*,
Respondents.

On Writ of Certiorari to the
United States Court of Appeals
for the Fourth Circuit

BRIEF FOR RESPONDENTS
UNITED STATES TOBACCO COMPANY, ET AL.

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QUESTION PRESENTED

Whether the Food and Drug Administration ("FDA") has jurisdiction to regulate the continued marketing of tobacco products, even though (1) its governing statute provides authority to regulate only products with a medical purpose, which tobacco products lack, and requires it to ban those that are "unsafe," and (2) Congress has enacted tobacco-specific statutes, which are premised on the continued marketing of tobacco products and which provide no role for FDA.

RULE 29.6 STATEMENT

Pursuant to Supreme Court Rule 29.6, Respondents submit the following corporate information:

1. Central Carolina Grocers, Inc., is a North Carolina corporation which is owned by one hundred ten (110) individuals and entities, none of whom individually own ten percent (10%) or more of the capital stock of the corporation. Central Carolina Grocers, Inc., has no non-wholly owned subsidiaries.

2. The parent companies of Conwood Company, L.P., are Conwood LLC; Conwood LLC-1; Conwood LLC-2; D. Aviation Services, Inc.; and Woodcon Holdings, Inc. Conwood Company, L.P., has no nonwholly owned subsidiaries.

3. J.T. Davenport, Inc., has no parent companies and has no nonwholly owned subsidiaries.

4. The parent company of National Tobacco Company, L.P., is North Atlantic Trading Company, Inc. National Tobacco Company, L.P., has no nonwholly owned subsidiaries.

5. North Carolina Tobacco Distributors Committee, Inc., has no parent companies and has no nonwholly owned subsidiaries.

6. The parent companies of The Pinkerton Tobacco Company are Swedish Match AB and Swedish Match North America Inc. The Pinkerton Tobacco Company has no nonwholly owned subsidiaries.

7. The parent company of Swisher International, Inc., is Swisher International Group, Inc. Swisher International Group, Inc., is wholly owned by Hay Island Holding Corporation, which is privately held. Swisher International, Inc., has no nonwholly owned subsidiaries.

8. The parent company of United States Tobacco Company is UST Inc. United States Tobacco Company has no nonwholly owned subsidiaries.

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IN THE
Supreme Court of the United States

No. 98-1152

FOOD AND DRUG ADMINISTRATION, *et al.*,
v. *Petitioners,*

BROWN AND WILLIAMSON TOBACCO CORP., *et al.*,
Respondents.

On Writ of Certiorari to the
United States Court of Appeals
for the Fourth Circuit

BRIEF FOR RESPONDENTS
UNITED STATES TOBACCO COMPANY, *ET AL.*

OPINIONS BELOW

The opinions below are identified in the Brief for the
Petitioners ("Pet. Br.") 1.

JURISDICTION

The basis for this Court's jurisdiction is set forth at
Pet. Br. 1.

STATUTORY PROVISIONS INVOLVED

This case involves the Federal Food, Drug, and Cos-
metic Act of 1938 ("FDCA" or "1938 Act"), Pub. L.
No. 75-717, 52 Stat. 1040, codified as amended at 21
U.S.C. §§ 301-397; the Federal Cigarette Labeling and
Advertising Act ("FCLAA"), Pub. L. No. 89-92, 79 Stat.

282 (1965), codified as amended at 15 U.S.C. §§ 1331-1341; the Comprehensive Smokeless Tobacco Health Education Act of 1986 ("CSTHEA"), Pub. L. No. 99-252, 100 Stat. 30, codified as amended at 15 U.S.C. §§ 4401-4408; and the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act ("ADAMHA Reorganization Act"), § 202, Pub. L. No. 102-321, 106 Stat. 323, 394-95 (1992), codified at 42 U.S.C. § 300x-26.¹

STATEMENT

Nature of the case. This is a lawsuit to invalidate FDA regulations that classify smokeless tobacco products and cigarettes as "drug delivery devices" under the FDCA. The respondents on this brief² are manufacturers of smokeless tobacco products, wholesale distributors whose products include smokeless tobacco, and an association of tobacco product wholesalers.³ Smokeless tobacco includes chewing tobacco and moist and dry snuff.

¹ The originally-enacted texts of the 1938 Act, and its predecessor, the Food and Drugs Act of 1906 ("1906 Act"), Pub. L. No. 59-384, 34 Stat. 768, are printed in the Appendix to this brief. Codified provisions of the FDCA as amended are in that Appendix and in the Appendix to Respondents' Brief in Opposition to Petition for a Writ of Certiorari ("Opp. Cert. App."). The originally-enacted and codified texts of the FCLAA and the CSTHEA and amendments, and the ADAMHA Reorganization Act, 42 U.S.C. § 300x-26, are set forth in the Opp. Cert. App.

² United States Tobacco Company; Conwood Company, L.P.; National Tobacco Company, L.P.; The Pinkerton Tobacco Company; Swisher International, Incorporated; Central Carolina Grocers, Incorporated; J.T. Davenport, Incorporated; North Carolina Tobacco Distributors Committee, Incorporated.

³ This brief presents the arguments that smokeless tobacco products are outside FDA's jurisdiction because they have no medical purpose and are therefore not "drugs" or "devices" under the FDCA, and because the CSTHEA precludes any contrary interpretation of the FDCA. The smokeless tobacco respondents agree with, and hereby rely on, the arguments made in the briefs of the other respondents.

Smokeless tobacco has a long history. The Copenhagen brand of moist snuff has existed since 1822. The "Garrett" trademark, used for moist and dry snuff products, is the oldest trademark in continuous use in the United States. In addition to the CSTHEA, federal laws relating to smokeless tobacco have included excise taxes and agricultural controls. *See* Comments of the Smokeless Tobacco Council, Inc., *et al.*, at 6-8, 53 (Jan. 2, 1996) (FDA Docket Nos. 95N-0253, 95N-0253J).⁴ Other restrictions have been imposed at the state or local level.

The FDCA of 1938. The FDCA replaced the Food and Drugs Act of 1906. The 1906 Act defined "drug" as "all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary" (*i.e.*, "compendial" products) and "any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease" (*i.e.*, "disease-treatment" products). Pub. L. No. 59-384, § 6, 34 Stat. at 769. Interstate commerce in adulterated or misbranded drugs was prohibited. §§ 2, 7, 8, 34 Stat. at 768, 769-71.

The 1906 Act was criticized because the "[d]efinition of drug does not include therapeutic devices, or drugs or devices intended to affect nonpathologic conditions of the body." 77 Cong. Rec. 5721 (1933). Consequently, the 1938 Act "drug" definition included a category for products "intended to affect the structure or any function of the body" (*i.e.*, "structure-or-function" products), Pub. L. No. 75-717, § 201(g)(3), 52 Stat. at 1041 (21 U.S.C. § 321(g)(1)(C)).⁵ A separate "device" definition, simi-

⁴ Lodged with the Court is a compilation of materials containing the cited pages of this and other documents referenced herein that may not be readily accessible.

⁵ When referring to early provisions of the FDCA or subsequent amendments to the FDCA in historical context, we cite the section

lar to the "drug" definition, was also added. § 201(h), 52 Stat. at 1041 (§ 321(h)(2)-(3)).

The structure-or-function category of the 1938 "drug" and "device" definitions filled a gap created by use of the word "disease" in the 1906 "drug" definition. FDA was uncertain of its legal authority over products that claimed to alleviate "nonpathologic" bodily conditions, such as obesity or short stature, that were undesirable but "that may not in themselves be diseases." *Food, Drugs, and Cosmetics: Hearings on S. 1944 Before a Subcomm. of the Senate Comm. on Commerce*, 73d Cong. 16 (1933) ("1993 Hearings") (statement of FDA Chief Walter G. Campbell). The structure-or-function category authorized FDA to regulate such medical products with respect to adulteration, misbranding, and safety. FDA did not ask for and was not given authority over non-medical products.

Congress amended the drug and device provisions of the FDCA many times. Uniformly, the amendments extended the FDCA framework to address additional issues raised by products with a medical purpose. Congress enacted separate laws to deal with health and safety issues of non-medical products, *e.g.*, the Consumer Product Safety Act, 15 U.S.C. §§ 2051-2084, the Federal Hazardous Substances Act, 15 U.S.C. §§ 1261-1278, and the Toxic Substances Control Act, 15 U.S.C. §§ 2601-2692.

Tobacco product legislation. Cigarettes and smokeless tobacco were among the non-medical products for which Congress enacted separate laws. In 1964, the Department of Health, Education, and Welfare ("HEW") issued

numbers of the law as enacted and provide a reference to the provision's section number as it currently appears in the United States Code ("U.S.C.") (1994 & Supp. III 1998). Otherwise, we cite the section numbers of the U.S.C. title in which the FDCA has been codified. Repetitive citations to the session laws are omitted.

the Surgeon General's Report on Smoking and Health, HEW, *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service* (1964). Congress conducted hearings.⁶ Despite the Surgeon General's conclusion that tobacco use was an "habituation" and that nicotine had "pharmacological actions . . . on the central nervous system" of a "stimulant or tranquilizing" nature, Report at 351, 354, HEW and FDA officials testified that the FDCA provided no jurisdiction over cigarettes. 1964 Hearings 56; 1965 Hearings 193. The Secretary of HEW cautioned that, if FDA had jurisdiction, it would have to ban cigarettes due to their adverse health effects. 1964 Hearings 18. Congress then enacted the FCLAA, which allowed cigarettes to be sold but with a prescribed label warning. Pub. L. No. 89-92, § 4, 79 Stat. at 283.⁷

In 1986, Congress enacted the CSTHEA. Modeled on the FCLAA, it allowed the sale of smokeless tobacco products but required warnings and prohibited broadcast advertising. Pub. L. No. 99-252, § 3, 100 Stat. at 30-32. Congress understood, as it did with the FCLAA, that FDA had no authority to regulate tobacco products. *See Tobacco Issues: Hearings on H.R. 2835, H.R. 760, H.R. 2950, and H.R. 3078, Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 99th Cong. 106 (1985) ("1985 Hearings")

⁶ *Cigarette Labeling and Advertising Relative to Health Problems Associated With Smoking: Hearings Before the House Comm. on Interstate and Foreign Commerce*, 88th Cong. (1964) ("1964 Hearings"); *Cigarette Labeling and Advertising: Hearings on H.R. 2248, H.R. 3014, H.R. 4007, H.R. 7051, and H.R. 4244 Before the House Comm. on Interstate and Foreign Commerce*, 89th Cong. (1965) ("1965 Hearings").

⁷ The brief of respondents Philip Morris Incorporated and Lorillard Tobacco Company more fully describes the FCLAA, including amendments to prohibit television and radio advertising.

("FDA claims it does not have the authority to regulate the sale of smokeless tobacco." (Statement of Rep. Mike Synar)).

The FDA tobacco proceeding. FDA regulates nicotine when marketed separately from tobacco for the medical purpose of helping smokers quit. However, FDA has never previously attempted to regulate nicotine in tobacco as a drug intended to "affect the structure or any function of the body" or suggested that cigarettes and smokeless tobacco have medical utility.

In 1995, FDA proposed regulations "restricting the sale and distribution of cigarettes and smokeless tobacco products." 60 Fed. Reg. 41,314 (1995). In an "analysis regarding jurisdiction," FDA determined that nicotine in tobacco products is a "drug" and that cigarettes and smokeless tobacco are "nicotine delivery devices" under the FDCA. *Id.* at 41,453.

The "objective of the proposed rule" was not to regulate tobacco products based on the supposed "drug" effects of nicotine, however, but "to reduce the death and disease caused by tobacco products," with "[t]he goal of . . . help[ing] the country achieve one of the objectives of 'Healthy People 2000,' . . . to reduce the number of children and adolescents who use tobacco products by roughly one half by the year 2000." *Id.* at 41,314.⁸ The FDCA was not designed for tobacco control. Therefore, FDA explained, "[it] examined many domestic and foreign tobacco control statutes, regulations, and legislation, as well as numerous studies and reports." 60 Fed. Reg.

⁸ "Healthy People 2000" is an annual report published by HEW's successor agency, the Department of Health and Human Services ("HHS"). The year 2000 target for smokeless tobacco use by minors—under 4 percent smokeless tobacco use by males age 12-17—has already been achieved. HHS, *Healthy People 2000 Review 1998-99* at 51, 54 (1999).

41,315. FDA concluded that "an effective program must address . . . (1) Restrictions on cigarette and smokeless tobacco sales that will make these products less accessible to young people; and (2) restrictions on labeling and advertising to help reduce the appeal of tobacco products to young people." *Id.* Accordingly, FDA proposed a federal 18-year minimum age requirement on retail tobacco sales and extensive restrictions on tobacco product advertising.

FDA's basis for regulating tobacco products was that the nicotine they contain is "intended to affect the structure or any function of the body," and is therefore a "drug" under 21 U.S.C. § 321(g)(1)(C) because nicotine has "foreseeable" physiologic effects, such as "addictiveness." *Id.* at 41,463-66. FDA did not find that these effects had, or were represented as having, a medical purpose in relieving undesirable "nonpathologic conditions" of the body. Nor did FDA explain how the physiologic effects of nicotine in tobacco products could be regulated under the FDCA's operative provisions relating to the "safety" and "effectiveness" of medical products.

FDA issued final regulations on August 28, 1996. 61 Fed. Reg. 44,396 (1996). Criticized for using the FDCA as an excuse for a tobacco control program, FDA pointed to such FDCA requirements as "good manufacturing practices" and "device listing," which it said could be applied to cigarettes and smokeless tobacco as if they were genuine "drugs" and "devices." *Id.* at 44,409-11. But FDA did not explain the basis for regulating these "dangerous" products, *id.* at 44,412, under the FDCA's "safety" provisions for devices, or how the "drug-like" effects of nicotine, on which jurisdiction was predicated, would be evaluated under the "effectiveness" provisions.

SUMMARY OF ARGUMENT

Two grounds for upholding the court of appeals are presented here: smokeless and other tobacco products are not "drugs" or "devices" under the FDCA, and a contrary interpretation is precluded by the CSTHEA.

I. The FDCA's structure-or-function definitions complemented the 1906 Act's compendial-product and disease-treatment definitions, providing FDA with comprehensive jurisdiction to regulate medical products. Congress's intent to limit FDA's authority to medical products is evident in the operative provisions of the FDCA relating to safety, effectiveness, adulteration, and misbranding, as well as in the legislative history of the "drug" and "device" definitions. Tobacco products have no medical purpose, and the FDCA does not contain provisions suitable to their regulation. Tobacco products, therefore, are not "drugs" or "devices" within the meaning of those terms in the statute.

FDA's contrary interpretation fails to relate the structure-or-function definitions to the FDCA's operative provisions, thus violating the "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Davis v. Michigan Dep't of Treasury*, 489 U.S. 803, 809 (1989). It also gives the FDCA an absurdly broad scope, subject to no legislatively-prescribed limitation on FDA's choice of products to regulate.

FDA's attempt to avoid the overbreadth problem by arguing that tobacco products are "quintessentially drug-like" is based on a false premise: that physiologic effects that "resemble" the effects of products intended for a medical purpose trigger FDCA "drug" and "device" juris-

diction even if the products producing those effects have no such purpose. If this premise were right, pepper spray would be a "drug" and an automobile seatbelt would be a medical "device."

II. The CSTHEA is Congress's program for addressing issues related to smokeless tobacco and health, and precludes FDA's interpretation of the FDCA as applicable to smokeless tobacco.

ARGUMENT

I. THE FDCA DOES NOT APPLY TO TOBACCO PRODUCTS.

A. The Structure Of The FDCA As A Whole Demonstrates That The "Drug" And "Device" Definitions Apply Only To Products With A Medical Purpose.

"In ascertaining the plain meaning of the statute, the court must look to the particular statutory language at issue, . . . [and] the language and design of the statute as a whole," *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1988) (citation omitted), as well as "its object and policy," *Dole v. United Steelworkers of Am.*, 494 U.S. 26, 35 (1990) (citations omitted). The "drug" and "device" definitions in chapter II of the FDCA serve the statute's operative provisions for "drugs" and "devices" in chapter V. The operative provisions enable FDA to evaluate, and take measures to assure the safety, effectiveness, and proper labeling of, products with a medical purpose. Therefore, the "drug" and "device" definitions are limited to products with a medical purpose.

As enacted (and as currently codified), chapter V provided that a drug was adulterated if "its strength differs from, or its quality or purity falls below, the standards set forth in" an official compendium (such as the *United States*

Pharmacopeia ("USP")), § 501(b) (21 U.S.C. § 351(b)), and that a noncompendial drug was adulterated if "its strength differs from, or its quality falls below, that which it purports or is represented to possess," § 501(c) (§ 351(c)). Chapter V provided that a drug with more than one ingredient was misbranded unless labeled with the "name of each active ingredient." § 502(e)(2) (§ 352(e)(1)(A)(ii)). It provided that a drug or device was misbranded unless it had "adequate directions for use" and warnings "against unsafe dosage or methods or duration of administration," § 502(f) (§ 352(f)), or if it was "dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling," § 502(j) (§ 352(j)). New drugs had to be shown to be "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling." § 505(d)(1) (§ 355(d)(1)).

Chapter V was designed only for medical products. It was medical products that raised concerns about "strength," "quality," and "purity," that required "adequate directions" and "warnings" against "unsafe dosages" and "methods of administration," and that had labeling that prescribed conditions of use under which a safety determination could be made as part of premarket review.

Amendments to chapter V have all related to medical products. In 1941 and 1945, Congress provided for FDA certification of insulin and penicillin drugs. Pub. L. No. 77-366, § 3, 55 Stat. 851; Pub. L. No. 79-139, § 3, 59 Stat. 463-64.⁹ The 1951 Prescription Drug Amendments, Pub. L. No. 82-215, § 1, 65 Stat. 648-49, established the

⁹ These provisions were repealed by the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), Pub. L. No. 105-115, § 125, 111 Stat. 2296, 2325.

requirement that a drug not "safe for use" except under a physician's supervision be dispensed only on prescription, 21 U.S.C. § 353(b)(1). Physicians do not prescribe drugs for other than medical purposes. The Drug Amendments of 1962, Pub. L. No. 87-781, § 102(b), 76 Stat. 780, 781, added the requirement that there be adequate evidence of effectiveness, in addition to evidence of safety, of a new drug under its labeled conditions of use, § 355(b)(1)(A). Products without a medical purpose cannot be evaluated under this standard.

The Medical Device Amendments of 1976, Pub. L. No. 94-295, § 2, 90 Stat. 539, 540141, required that all devices be classified "to provide reasonable assurance of the safety and effectiveness of the device," 21 U.S.C. § 360c(a)(1), "with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and . . . weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use," § 360c(a)(2)(B)-(C). Products without a medical purpose cannot be evaluated under this standard.

Recent amendments to chapter V also pertain to medical drugs, *e.g.*, pharmacy compounding of drugs, 21 U.S.C. § 353a; pediatric studies of drugs to generate information on how "the use of a new drug in the pediatric population may produce health benefits," § 355a; fast track products "intended for the treatment of a serious or life-threatening condition," § 356; and discontinuance by the sole manufacturer of a drug that is "life-supporting" or "life-sustaining," § 356c.

Chapter V is the core of the FDCA's authority for drugs and devices; the definitions are the means for implementing chapter V and "must be understood against the backdrop of what Congress was attempting to accom-

plish." *Reves v. Ernst & Young*, 494 U.S. 56, 62-63 (1990). Chapter V is designed and intended for products with a medical purpose.

B. FDA Improperly Focused On The "Drug" And "Device" Definitions In Isolation From The FDCA As A Whole.

FDA explained at length how the FDCA's drug and device provisions relating to manufacturing procedures, recordkeeping, and product listing could be applied to tobacco products, 61 Fed. Reg. at 44,409-11—as, indeed, they could be applied to any manufactured product, including ballpoint pens and automobiles—but it did not explain how the FDCA's safety and effectiveness requirements could rationally be used to regulate cigarettes and smokeless tobacco as medical products having the physiologic effects FDA relied on as the basis for its exercise of jurisdiction.

The Agency's inability to articulate a rational relationship between the FDCA's core operative provisions for assuring the safety and effectiveness of drugs and devices and the purported "structure-or-function" effects of tobacco products that supposedly subject them to FDCA jurisdiction demonstrates that there is none. FDA did not view the "drug" and "device" definitions as integral parts of chapter V's program for regulating medical products, but as a source of language useful for rationalizing its pursuit of tobacco control.

FDA's strategy is improper. "[T]he words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Davis*, 489 U.S. at 809. The definitions of "drug" and "device" are not grants of jurisdiction to regulate anything within their literal language. Rather, they explain what the defined terms refer to when used in the operative provisions of

the FDCA. FDA's "jurisdiction" consists of its authority to administer those provisions.

As the court of appeals recognized, *see* Appendix to Petition for a Writ of Certiorari 18a-30a, "drugs" and "devices" in chapter V are products that can sensibly be regulated by applying statutory provisions that require "adequate directions" for use, labeling disclosure of "active ingredients," and determinations of "safety" and "effectiveness" based on the "weighing [of] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use," 21 U.S.C. § 360c(a)(2)(C). The "drugs" and "devices" referred to in chapter V are products with a medical purpose. Because tobacco products, including the nicotine they contain, have no medical purpose, they are not "drugs" and "devices" within the meaning Congress intended those terms to have.

The Government contends that "the structure of the Act as a whole" does not "detract[] from" FDA's interpretation of the definitions. Pet. Br. 8. The quoted statement refers to FDA's explanation (*see* 61 Fed. Reg. 44,412-13) for why classifying "dangerous" tobacco products as "drug delivery devices" would not require them to be banned under the operative provisions of the FDCA, *see* Pet. Br. 30-37. This is not a "whole act" analysis but its antithesis: an attempt to explain away a paradox created by FDA's interpretation of the "drug" and "device" definitions in isolation from the "whole act," which includes the operative provisions of chapter V. The Government's misleading attempt to suggest that FDA considered the "structure of the Act as a whole," *id.* at 30, underscores both the importance of that interpretational methodology and the significance of FDA's failure to apply it in this case.

C. The Legislative History Of The 1938 Act Confirms That The Structure-Or-Function Definition Applies Only To Medical Products.

The legislative history of the 1938 Act demonstrates that the only problem Congress addressed by adding the structure-or-function category to the "drug" definition, and by adding a parallel "device" definition, was that FDA's authority did not reach all medical products.

The first bill, S. 1944, 73d Cong. (1933), was introduced on June 12, 1933, by Senator Royal S. Copeland, who became the FDCA's principal Senate sponsor. The bill defined "drug" as in the 1906 Act, but added a structure-or-function category. § 2(b). Devices were included within the "drug" definition. *Id.* Senator Copeland placed a memorandum in the record comparing S. 1944 with the 1906 Act. It noted that (unlike S. 1944) the 1906 Act's "drug" definition "does not include therapeutic devices, or drugs or devices intended to affect nonpathologic conditions of the body." 77 Cong. Rec. 5721. FDA Chief Campbell stated at hearings on S. 1944 that the purpose of the structure-or-function definition was to authorize regulation of antifat remedies, which "cannot be alleged to be treatments for diseased [sic] conditions," and devices to "correct physiological or anatomical defects that may not in themselves be diseases." 1933 *Hearings* 16.¹⁰

S. 1944 was replaced by S. 2800, 73d Cong. (1934). The drug definition was the same as in S. 1944, but, consistent with the legislators' understanding that the definition identified medical products, clarified that "drug"

¹⁰ To the same effect, see *Food, Drugs, and Cosmetics: Hearings on S. 2800 Before the Senate Comm. on Commerce*, 73d Cong. 516 (1934) ("1934 *Hearings*"); *Food, Drugs, and Cosmetics: Hearing on H.R. 6906, H.R. 8805, H.R. 8941 and S. 5 Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 74th Cong. 55-56 (1935).

was defined for purposes of the Act and "not to regulate the legalized practice of the healing art," S. Rep. No. 73-493, at 2 (1934).

During the floor debate, Senator Copeland criticized the 1906 "drug" definition:

The present [1906] law defines drugs as substances or mixtures of substances intended to be used for the cure, mitigation, or prevention of disease. This narrow definition permits escape from legal control of all therapeutic or curative devices like electric belts, for example. It also permits the escape of preparations which are intended to alter the structure or some function of the body, as, for example, preparations intended to reduce excessive weight.

78 Cong. Rec. 8960 (1934).

A revision of S. 2800, introduced as S. 5, 74th Cong. (1935), created separate but similar definitions for "drugs" and "devices," S. Rep. No. 74-646, at 1 (1935). When S. 5 was reported out of committee, the definitions were unchanged, except that the clause relating to "the healing art" had been removed as "unnecessary," H.R. Rep. No. 74-2755, at 5 (1936). The definitions would address such problems as "[d]eadly drugs intended for reducing purposes or otherwise to affect the structure or function of the body, which do not fall within the narrow definition of drug in the present [1906] law" and "[d]angerous and worthless therapeutic devices." *Id.* at 3.

Further proceedings in 1936 and 1937 produced a slightly modified bill, reported in the House on April 14, 1938, 83 Cong. Rec. 5465 (1938). The House Report stated that the bill would close "serious loopholes" in the 1906 Act, in that, among other things, "[t]herapeutic devices are brought under control" and "[d]rugs . . . for remedying underweight or overweight or for otherwise

affecting bodily structure or function are subjected to regulation." H.R. Rep. No. 75-2139, at 1-2 (1938). The bill was signed into law on June 25, 1938. Pub. L. No. 75-717, 52 Stat. 1040 (1938).

This legislative history demonstrates that the problem Congress perceived and addressed was that non-compensatory products intended for medical purposes, but not for "diseases," escaped regulation under the 1906 Act. Congress closed that "loophole" by adding the structure-or-function category to the "drug" and "device" definitions.

The Government relies on some of the same legislative history as "additional support" for FDA's conclusion that tobacco products are drugs and devices under the FDCA. Pet. Br. 20-21. It contends that "Congress understood" that the expanded "drug" definition "would reach well beyond weight-loss products and cover other products intended to affect the structure or function of the body." *Id.* at 20 (citing the House Report reference to drugs "for remedying underweight or overweight or for otherwise affecting bodily structure or function," H.R. Rep. No. 75-2139, at 2). As the Government's own explanation makes clear, however, the word "otherwise" refers to products for different *medical* purposes: shoulder braces, radium belts, crutches. Pet. Br. 21. Congress regarded the structure-or-function definition as "an inclusive, . . . wide definition," *id.*, but the definition "inclusively" covered medical products, not all products that, literally, are intended to "otherwise" affect the structure or function of the body.

D. The Structure Of The Definitions Is Contrary To FDA's Interpretation.

The Government contends that the "structure" of the definitions supports the conclusion that they encompass products with no medical purpose, such as cigarettes and

smokeless tobacco. *Id.* at 17-19. It notes that several FDCA definitions exempt products that would otherwise be included, but tobacco products are not exempt from the "drug" and "device" definitions. *Id.* at 18-19.

This misconceives the issue. The issue is whether the "drug" and "device" definitions apply to tobacco products in the first instance. They do not. The structure of the FDCA as a whole and its legislative history demonstrate that Congress intended the "drug" and "device" definitions to apply only to products with a medical purpose. There was therefore no need for the definitions to exempt tobacco products. Moreover, neither when the definitions were enacted nor thereafter did Congress have the slightest inkling that FDA would consider tobacco products to be within the definitions. FDA itself, on numerous occasions after 1938, interpreted the definitions as inapplicable to tobacco products, obviating the need for Congress to add an exemption when federal regulation of tobacco and health began in 1965.

There is a pertinent structural aspect of the "drug" and "device" definitions that the Government ignores. Each definition includes three categories: compensial products, disease-treatment products, and structure-or-function products. The compensial-products category has always been interpreted as including only products with a medical purpose, even though the designated compendia include substances that may have no such purpose. See 1934 Hearings 514-15;¹¹ *National Nutritional Foods Ass'n ("NNFA") v. Mathews*, 557 F.2d 325, 337 & n.11 (2d Cir. 1977). The disease-treatment category has never

¹¹ According to FDA Chief Campbell, whiskey was listed in the USP. 1934 Hearings 514. Mr. Campbell disagreed with a suggestion to add "medicinal use" to the compensial-product definition because FDA did not interpret it as applicable unless a compensial substance was to be "used for drug purposes." *Id.* at 514-15.

been viewed as applying other than to products with a medical purpose. It follows (and the legislative history confirms) that the third category was for products with similar characteristics, *i.e.*, products whose intended structure-or-function effects have a medical purpose. *See, e.g., Gustafson v. Alloyd Co.*, 513 U.S. 561, 575-76 (1995); *id.* at 586-87 (Thomas, J., dissenting) (*noscitur a sociis*).

FDA's alternative interpretation is that the structure-or-function category includes all products that, literally, are "intended to affect the structure or any function of the body." So interpreted, the category includes a vast universe of manufactured goods, such as thermal pajamas, exercise equipment, and home air conditioners. The Government has conceded that FDA's interpretation would subject such products to the drug and device provisions of the FDCA, but its only response to this untenable result is that (as it stated to the lower court) "FDA may, in its discretion, decline to regulate them." Appellee and Reply Brief for Food and Drug Administration, *et al.* 20.

This response does not acknowledge, much less identify, any legislatively-sanctioned principle for distinguishing between products FDA may and those it may not regulate. Without such a principle, it will be FDA instead of Congress that determines the scope of the FDCA. This is not a role FDA may play. *See, e.g., Bureau of Alcohol, Tobacco & Firearms v. Fed. Labor Relations Auth.*, 464 U.S. 89, 97 (1983) (agencies may not make "'major policy decisions properly made by Congress'") (citation omitted).

FDA's response also misses the point. That FDA's interpretation would allow it to regulate the "safety" and "effectiveness" of home air conditioners demonstrates that the interpretation is flawed, *cf. Green v. Bock Laundry Mach. Co.*, 490 U.S. 504, 509-10 (1989) (rejecting a

"literal reading [that] would compel an odd result"), not that FDA needs to be wise in selecting which products to regulate.¹²

The Government relies on *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784 (1969). Pet. Br. 22-23. There, the Court said, "Congress fully intended that the Act's coverage [under the "drug" definition] be as broad as its literal language indicates—and equally clearly, broader than any strict medical definition might otherwise allow." 394 U.S. at 798.

Bacto-Unidisk is not precedent for an interpretation of the structure-or-function definitions that, like FDA's for tobacco products, ignores the context of the FDCA. Indeed, the case supports our argument here.

The product at issue was an antibiotic sensitivity disk, used by physicians to choose the most effective antibiotic for medical treatment. *Id.* at 784. The disk was exposed to fluids taken from, but did not physically contact, the patient. *Id.* at 787. FDA classified the disk as a "drug" in order to require premarket review. *Id.* at 788. Except for its physical form, the disk was a conventional "disease-treatment" drug. Its function and purpose were within the traditional scope of FDA's regulatory responsibilities for assuring the safety and effectiveness of medical prod-

¹² Compare *United States v. Sullivan*, 332 U.S. 689, 694 (1948): "The scope of the offense [of misbranding under the FDCA] which Congress defined is not to be judicially limited by envisioning extreme possible applications. . . ." In *Sullivan*, there was no question as to the proper interpretation of the statutory text, only an issue as to whether FDA could be trusted not to misapply it to petty offenses. Here, the issue is whether FDA has properly interpreted the drug and device provisions to determine which products are properly subject to them. Whether FDA has correctly concluded that tobacco products are "drugs" and "devices" does not depend on whether its use of discretion can be defended, but on what the statutory text means.

ucts. Unlike tobacco products, the disk raised no issue of extending the FDCA into new product areas. It presented a "gap-filling" issue of the sort agencies are entrusted to resolve.

The lower courts held that the disk was not a "drug" within the disease-treatment definition, because "the commonly accepted view of physicians generally" was that a substance not "taken into or applied to the body" was not considered "medically" to be a drug. See *United States v. An Article of Drug . . . Bacto-Unidisk*, 392 F.2d 21, 22-23 (6th Cir. 1968). It was that limitation this Court found unjustified by the language of the "drug" definition. 394 U.S. at 792-93. But the Court looked beyond the "drug" definition's "literal language." It examined the legislative history of the FDCA, and the "fit" between the operative provision FDA wished to use—requiring premarket review—and the problem it wished to solve—assuring the "safety" and "efficacy" of a medical product. *Id.* at 793-98. The Court did not imply—much less say—that the "drug" definition encompasses non-medical products. Indeed, it was because the sensitivity disk was a medical product that the Court upheld FDA's interpretation. *Bacto-Unidisk* supports our interpretation that the structure-or-function definition, read in the context of the FDCA and in light of its legislative history, includes only products with a medical purpose, which tobacco products lack.

E. On FDA's Own Findings, Tobacco Products Are Not Structure-Or-Function Drugs Or Devices.

FDA "found" that nicotine "causes and sustains addiction," "causes other psychoactive . . . effects, including tranquilization and stimulation," and "controls weight." 61 Fed. Reg. 44,661; Pet. Br. 3-5. However, FDA did not find that any of these effects, if caused by nicotine in

tobacco, serves a medical purpose. FDA's findings show only that nicotine "affects the structure or any function of the body" in the literal sense.¹³

The Government insists that the effects of nicotine in tobacco are similar to the effects of some medical products: "FDA found that those effects on the structure and function of the body are quintessentially drug-like, identical to those FDA has found in numerous other products that it regulates under the Act, including stimulants, tranquilizers, appetite suppressants, nicotine replacement products, and narcotics used to treat addiction." Pet. Br. 3-4. These effects "mirror" those of the medical products alluded to, *id.* at 23, and have the "classic characteristics of drugs and devices subject to regulation under the Act," *id.* at 24. As a consequence, tobacco products have a "resemblance" to "products regulated as drugs and devices by the FDA." *Id.*

It is not an accepted principle of interpretation that, if a statute specifies a thing or activity an agency is to regulate, the agency has authority to regulate all things and activities that are "found" to have a "resemblance" to it. Many manufactured products are similar to drugs and devices, but the similarity does not bring them within FDA's jurisdiction. Automobile seatbelts are, using FDA's vocabulary, "quintessentially device-like," in that they have the same physical effect as, for example, patient "protective restraints," which are regulated by FDA as medical devices, 21 C.F.R. § 880.6760 (1999). Under

¹³ Under the FDCA's "drug" and "device" definitions, any effects must also be "intended" by the manufacturer or other vendor. 21 U.S.C. §§ 321(g)(1), 321(h). The brief of respondent Brown and Williamson Tobacco Corporation demonstrates that FDA has failed to show that the effects it has identified are "intended." This brief demonstrates that, even if those effects were "intended," they would be outside the definitions because they do not serve a medical purpose.

FDA's theory, seatbelts, which are regulated under laws administered by the National Highway Traffic Safety Administration,¹⁴ would be subject to concurrent jurisdiction as devices under the FDCA. Chemical Mace similarly would be subject to FDA jurisdiction because it has the "classic characteristics" of topical irritant drugs, *e.g.*, capsicum oleoresin, which have been regulated by FDA for decades. *See* 48 Fed. Reg. 5852, 5868 (1983) (listing "capsicum oleoresin," among other chemicals, as a safe and effective "counterirritant" ingredient in topical analgesic over-the-counter drugs). Capsicum oleoresin is the ingredient in Mace-like personal protection "pepper sprays."¹⁵

The Government's decision to play up the "drug-like" effects of nicotine in tobacco products betrays its recognition that to interpret the structure-or-function definition in accordance with its "plain language" and without regard to medical purpose would extend its boundaries too far. The Government therefore analogizes the effects of nicotine in tobacco products to the effects produced by

¹⁴ *See* 49 U.S.C. § 30102(a)(7) (defining "motor vehicle equipment"). The National Traffic and Motor Vehicle Safety Act does not explicitly exclude "devices" from the definition of "motor vehicle equipment," and the FDCA does not explicitly exclude motor vehicle equipment from the "device" definition.

¹⁵ *See Public Sale of Protective Chemical Sprays: Hearing Before the Consumer Subcomm. of the Senate Comm. on Commerce*, 91st Cong. 3 (1969). A witness at the hearing said that, because Mace "is a chemical which goes into the body and can alter the structure or function of the body," it should be regulated as a drug. *Id.* at 7. FDA's Chief Counsel agreed that Mace fit the literal language of the structure-or-function "drug" definition, just as "pistols and bullets are intended to affect the function or structure of the body in the same way." *Id.* at 37. However, he "concluded that the products [Mace and other self-protection chemical sprays] could not properly be classified as drugs under the definition in the Food, Drug, and Cosmetic Act." *Id.*

drugs that *do* have a medical purpose. The analogy is false. Whether a product is "quintessentially" a "drug" or a "device" does not depend on what it does, but on what it is intended to accomplish. Both a bayonet and a scalpel cut flesh, but only one of them is a medical device.

Conversely, FDA has the authority to regulate products intended to be used for medical purposes as "drugs" and "devices" without regard to the nature, or even the existence, of their actual physical effects. *See, e.g., United States v. 23 . . . Articles*, 192 F.2d 308 (2d Cir. 1951) (phonograph record a "device"); *Bradley v. United States*, 264 F. 79 (5th Cir. 1920) (water a "drug" under 1906 Act "disease-treatment" drug definition).

Under the FDCA there is no such thing as an inherently, or "quintessentially," drug-like or device-like effect that, standing by itself, triggers FDA jurisdiction. "[T]he statutory definition of a substance under the Act does not depend on any inherent properties of the substance, but rather, it depends on how the vendor of the substance intends the substance to be used." *United States v. Two Plastic Drums*, 791 F. Supp. 751, 753 (C.D. Ill. 1991) (citation omitted), *aff'd*, 984 F.2d 814 (7th Cir. 1993). The effects of nicotine in tobacco FDA characterizes as quintessentially drug-like do not have inherently medical purposes that transform tobacco products into FDA-regulated "drug delivery devices."

"*Addictiveness.*" FDA found that nicotine in tobacco products "causes and sustains addiction." 61 Fed. Reg. 44,661. Indeed, FDA went so far as to suggest that

[t]here is . . . a basis for finding that these products are "effective" for adults who are addicted to tobacco products because such products sustain with great efficacy the individual's continued need for the active ingredient nicotine . . . [and] are effective for

preventing withdrawal symptoms in individuals addicted to nicotine in much the same way that methadone is effective in preventing withdrawal.

Id. at 44,413.¹⁶

Drugs such as morphine have addictive properties. These drugs are not within the FDCA "drug" definition because they are addictive, however, but because their other pharmacological properties have a medical purpose (e.g. analgesia). Indeed, addictiveness is a toxic side effect,¹⁷ and toxicity is not a basis for categorizing a product as a "drug." *NNFA v. Mathews*, 557 F.2d at 334-35. The medical benefits of an addictive drug must outweigh the risk of addiction to warrant approval under the FDCA. See 21 U.S.C. § 355(d).

FDA's result-oriented argument that tobacco products might somehow be considered "effective" under the FDCA due to their "addictiveness" is nonsensical and perverse. The only recognized medical use of nicotine is in FDA-approved smoking-cessation drugs, such as Nicorette gum. Those products provide nicotine in a form that does not involve the use of tobacco, ultimately to stop nicotine use altogether, including the nicotine in the drug products. It is not reasonable for FDA to contend that a cigarette might be considered a "drug delivery device" for treating cigarette smoking, or that nicotine in tobacco products might be considered "effective" for "sustaining" the very

¹⁶ FDA did not convert this "basis" into a "finding," and its use of quotation marks around "effectiveness" signals that it was using that word with a meaning other than the statutory meaning.

¹⁷ Methadone is approved as a drug under the FDCA for use in treating heroin addiction because it is a safer source of the addictive properties of heroin, and therefore can be used in place of heroin to improve the patient's medical status. However, neither FDA nor any other government agency recommends the use of methadone for the purpose of experiencing its addictiveness when there is no heroin addiction for methadone addiction to replace.

"addiction" it supposedly causes, and which drugs like Nicorette are intended to combat. If FDA were correct, methadone would be unnecessary because heroin could be considered an "effective" drug for the treatment of heroin addiction.

When it comes to tobacco, FDA views the FDCA not as a legislative charter but as a compendium of exploitable terminology. Just as the Agency interprets the structure-or-function definition in isolation from the operative provisions for drugs and devices, it interprets drug "effectiveness" without regard to the requirement that a drug be "effective" for a beneficial purpose, and that it also be "safe." This "words and phrases" approach allows FDA to apply a veneer of plausibility to an absurd proposition—nicotine in tobacco is an effective "drug" because it sustains "addiction" to nicotine in tobacco. But it cannot hide the Agency's failure to interpret the FDCA as a coherent legislative program for regulating medical products.

"*Tranquilization and stimulation.*" FDA's finding that nicotine in tobacco products has the structure-or-function properties of "tranquilization and stimulation," 61 Fed. Reg. 44,661—an observation made by the Surgeon General in 1964—is opportunistic. FDA has no intention of regulating cigarettes and smokeless tobacco as medically useful tranquilizers and stimulants, and would never permit them to be labeled for those purposes. Rather, FDA describes physiological effects using evocative terms to make them sound "drug-like."¹⁸

¹⁸ FDA purported to analyze the "safety" of banning tobacco products used by "addicted" adults, taking into account the effects on adult users, treatment demands on the health care system, and possible smuggling, *id.* at 44,413. That is not a proper "safety" analysis under the FDCA, see Brief For Respondent R.J. Reynolds Tobacco Company, Part I.B.1; but, even if it were, FDA did

"Tranquilization" and "stimulation" are medical uses of some FDA-regulated drugs. But a medical use cannot be inferred solely from a physiological effect, *e.g.*, the cutting of flesh. The effects FDA found nicotine to have were "arousal-reducing" and "arousal-increasing" effects. 60 Fed. Reg. 41,536. Considered solely as effects, properties that cause drowsiness or agitation are not inherently medical. FDA obscures this fact by using "tranquilizer," "sedative," and "stimulant," words used to refer not just to effects but also to categories of FDA-regulated drugs. It is circular to use words that imply a medical purpose to describe an effect that is, according to FDA, inherently a "drug" effect without regard to its purpose.

"Weight control." FDA found that "[n]icotine in cigarettes and smokeless tobacco controls weight." 61 Fed. Reg. 44,661. This finding, too, is tautological: the word "control" implies the very medical purpose FDA contends is inherent in the effect. Although an effect on body weight can be given a medical purpose by incorporating a substance that has that effect in a product labeled for "weight control" or "slenderizing," an effect on body weight in the abstract has no purpose, medical or otherwise.

Thus, FDA's finding that nicotine in tobacco "controls weight," even if true as a physiological matter, could at most support the argument that "actual consumer use" can be evidence of an "intended drug use" of a product. FDA makes an "actual use" argument, *see id.* at 44,662,

not apply it, or any other safety analysis, to the "tranquilization" and "stimulation" effects of tobacco products. If FDA believes that cigarettes and smokeless tobacco were "sufficiently safe" for continued marketing to adults, the Agency should be prepared to review and approve over-the-counter labeling for cigarettes and smokeless tobacco as tranquilizer and stimulant medical devices, including indications for use, dosage instructions, warnings, and contraindications.

but the underlying finding is legally inadequate. Even under judicial dicta, the only circumstance in which consumer use of a product is evidence of "intended drug use" is when a product is used "almost exclusively for therapeutic purposes," *NNFA v. Mathews*, 557 F.2d at 334, and there is a lack of a recognized non-drug use, *id.* If that is not the case, actual use does not determine "intended use." FDA made no finding of "almost exclusive" use of tobacco products for "weight control."¹⁹ In this very proceeding, it concluded that weight control is merely one of "a variety of ancillary drug effects" for which "[c]onsumers also use tobacco." 60 Fed. Reg. at 41,581.

The Government argues that, if nicotine is known to control body weight (or sedate or tranquilize, or cause addiction), manufacturers of cigarettes and smokeless tobacco products should not be free from FDA regulation merely because "they refrain from making such claims." Pet. Br. 24-25. This argument underscores FDA's distortion of the FDCA. Under FDA's theory, the known "intended" uses of tobacco products are *required* to be "claimed" in the labeling of cigarettes and smokeless tobacco. *See id.* at 27 n.5. Thus, if "weight control" actually were an "intended" drug use of nicotine in tobacco products, its omission from their labeling would cause them to be "misbranded drugs." *See* 21 U.S.C. § 352(f)(1); 21 C.F.R. § 201.5. However, inclusion of "weight control" as an indication would cause them to be unapproved "new drugs" because nicotine is not "generally

¹⁹ FDA's "intended use" findings, 61 Fed. Reg. 44,661-62, do not distinguish among the three categories of physiologic effects the Agency characterizes as "quintessentially drug-like" ("addictiveness," "tranquilization/stimulation," "weight control"). Nothing in the administrative record even purports to constitute a finding of intended use of smokeless tobacco for weight control purposes; and, as to cigarettes, the record shows only that many people cite weight control as one reason for smoking. 60 Fed. Reg. 41,580.

recognized" as safe and effective for that use. See 21 U.S.C. § 321(p)(1). Following the logic of the FDCA, as FDA normally would, manufacturers would be forced to submit approval applications to establish that tobacco products are "safe and effective" slenderizers—or remove them from the market. See *United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847, 852-53 (D.N.J. 1959).

But the Government does not extend this logic to its natural conclusion, because the effects of nicotine on body weight, if any, are not "drug" or "device" effects amenable to the standards and controls of chapter V. They are a pretext for FDA's assertion of jurisdiction.

F. FDA Does Not Regulate Non-Medical Products As Drugs And Devices.

In the 61-year history of the FDCA, FDA has taken hundreds of thousands of actions, formal and informal, against a diverse array of products.²⁰ FDA cannot deny that its consistent practice has been to apply the drug and device provisions only to products with a medical purpose.²¹

FDA implied in the rulemaking that it has routinely applied the structure-or-function definition to products "with cosmetic, recreational, economic, or other non-

²⁰ The Agency has filed over 67,000 seizure actions since 1938 as demonstrated by its sequential numbering of all civil seizure actions. See, e.g., *FDA Consumer* (July-Aug. 1999), Summaries of Court Actions, at 38, 39 (*Acne Cream*, FDC No. 67,231). In fiscal year 1998, FDA issued 36,724 import detentions, 905 warning letters, and 8038 lists of adverse inspectional observations, and supervised 3532 recalls. HHS, *The Enforcement Story: Fiscal Year 1998* at 220 (undated).

²¹ Isolated examples, lacking factual context, of uncontested actions, see 60 Fed. Reg. 41,527-28 (khat, "caine"), are not precedent (Pet. Br. 29) for expanding the scope of FDA's jurisdiction to include non-medical products.

therapeutic purposes." 61 Fed. Reg. 44,677. The examples cited, however, were products with the immediate purpose of improving the physical condition of the body. For instance, FDA gave tanning booths as an example of a product "with non-therapeutic, but pharmacological effects," 60 Fed. Reg. 41,468, and "cosmetic, recreational . . . or other nontherapeutic purposes," 61 Fed. Reg. 44,677. Under the FDCA, FDA does not regulate "tanning booths," but "ultraviolet lamps for tanning." 21 C.F.R. § 878.4635. FDA created this category of convenience because "the various therapeutic uses for sunlamp products, including treatment of fungal diseases, vitamin D production, treatment of psoriasis, and treatment of acne, cannot be readily separated from the tanning function," 44 Fed. Reg. 65,352, 65,353 (1979), and because the Agency has separate authority to regulate non-therapeutic sunlamps as radiation-emitting products under a different statute, see *id.* at 65,356. FDA also cited an animal euthanasia drug, on the ground that it was "intended to induce death in animals by humane means—an intended use that is indisputably not therapeutic." 61 Fed. Reg. 44,678. This is too narrow a view. From the perspective of the ethical treatment of animals, a drug that brings about the necessary or inevitable death of an animal in a humane fashion indisputably has a medical purpose.²²

Consistent with the FDCA's objective of protecting the public health, *Bacto-Unidisk*, 394 U.S. at 798, FDA has taken a broad view of what constitutes a medical purpose so as to bring within the "drug" and "device" definitions

²² 21 U.S.C. § 360b, for "new animal drugs," applies to products that have a medical purpose both in treating animals and in improving their growth or output (by making the animals healthier) for economic reasons.

a wide range of health-benefiting products. However, FDA cannot give those definitions a construction that has no limits at all. *See, e.g., Rodriguez v. United States*, 480 U.S. 522, 526 (1987). Nor is that necessary. Other agencies, with their own remedial statutes, also have the responsibility and authority to take action to protect the public health. In the improbable event, for example, that anyone tried to market a nicotine product for non-medical use—such as a nicotine inhaler promoted for “breathing pleasure,” *see* Certiorari Reply Brief for the Petitioners 5—any safety issues could be promptly dealt with under appropriate federal laws, such as the Consumer Product Safety Act.

FDA’s responsibilities are broad and vitally important, but they are nevertheless limited by the intent of Congress as embodied in the FDCA: “In our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the [FDCA] beyond the point where Congress indicated it would stop.” 62 *Cases . . . of Jam v. United States*, 340 U.S. 593, 600 (1951).

II. THE CSTHEA PRECLUDES FDCA JURISDICTION OVER SMOKELESS TOBACCO PRODUCTS.

In addition to being invalid on its own terms, FDA’s new interpretation of the FDCA has been precluded by specific laws relating to tobacco and health—the FCLAA and the CSTHEA. The history of these laws, set forth at pp. 4-6, *supra*, and in the brief of respondents Philip Morris Incorporated and Lorillard Tobacco Company, demonstrates that Congress acted to do what FDA told Congress it had no authority to do: establish health-related requirements for tobacco products.²³

²³ *See 1965 Hearings* 193 (“[FDA] has no jurisdiction under the [FDCA] over tobacco, unless it bears drug claims.” (Statement of

FDA cannot now override Congress’s tobacco-specific statutes by reversing its position. The “proper inquiry is how best to harmonize” the FDCA with those later-enacted statutes. *United States v. Estate of Romani*, 118 S. Ct. 1478, 1486 (1998). “Th[e] classic judicial task of reconciling many laws enacted over time, and getting them to ‘make sense’ in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute.” *United States v. Fausto*, 484 U.S. 439, 453 (1988).

The Government trivializes the FCLAA and CSTHEA as “several statutes that deal with tobacco in certain specific respects.” Pet. Br. 44. “Like FCLAA, the Smokeless Tobacco Act simply requires certain warnings on packages and precludes federal agencies, including FDA, from requiring different ones.” *Id.* at 46. The FCLAA and CSTHEA are far more than that. They constitute Congress’s enacted judgments about how tobacco products should be regulated at the federal level in relation to health issues.²⁴

The CSTHEA, modeled on the FCLAA, bans broadcast advertising of smokeless tobacco products, 15 U.S.C. § 4402(f); requires health warnings on packages and in most advertising, § 4402(a); establishes a mandatory warning format, § 4402(b); authorizes the Federal Trade Commission, not FDA, to issue regulations, § 4402(c); requires ingredient reporting to HHS, § 4403; requires

FDA Deputy Comm’r Winton B. Rankin)); 1985 *Hearings* 106 (“FDA claims it does not have the authority to regulate the sale of smokeless tobacco.” (Statement of Rep. Mike Synar)).

²⁴ Congress encouraged the States to develop programs to curtail underage tobacco use. 42 U.S.C. § 300x-26. As explained in the brief of respondents National Association of Convenience Stores and Acme Retail Incorporated, Congress intended that States take the lead in this area, an objective thwarted by FDA’s assertion of jurisdiction.

HHS to "establish and carry out a program to inform the public of any dangers to human health resulting from the use of smokeless tobacco products," by, among other things, making "programs, materials, and announcements available to States, local governments, school systems, [and] the media," § 4401(a)(1); and requires HHS to report biennially to Congress, including any "recommendations for legislation and administrative action that HHS considers appropriate," § 4407(a).

The CSTHEA was enacted to deal with the same issues FDA contends are the primary target of its own regulations under the FDCA: the use of smokeless tobacco by minors, and the supposed influence of advertising and promotion on minors' decision to use the product. "[A] major reason for the development of a legislative proposal is the alarming incidence of use by children." S. Rep. No. 99-209, at 4 (1985). A principal sponsor stated that the CSTHEA banned broadcast advertising "due to concern about the impact of such advertising upon youth," 132 Cong. Rec. 1330 (1986) (statement of Rep. Henry Waxman), and that the educational efforts "are especially critical at the primary and secondary school levels where young people are most vulnerable and the pressure to begin smokeless tobacco use is strong." *Id.* Congress was also well aware that nicotine in tobacco was considered to have "addictive properties," *id.* at 1331 (statement of Rep. Waxman), and, in particular, of the belief that "smokeless tobacco is addictive," *id.* at 1333 (statement of Rep. Synar).

The CSTHEA covers a wide range of issues relating to smokeless tobacco and health. The program was the result of congressional decisions both about what should be required (a ban on broadcast advertising, warnings in print advertising) and what should not be required

(limits on print advertising format, a ban on smokeless tobacco sales altogether). FDA's conclusion that its regulations are justified because "[t]he statutes enacted by Congress for regulation of tobacco products do not amount to a comprehensive scheme," 61 Fed. Reg. 44,547, is in truth an administrative repudiation of Congress's policy judgment as to how "comprehensive" federal regulation in this area should be. FDA believes it should be more comprehensive than the CSTHEA provides, but Executive Branch agencies may not second-guess Congress. Although, in FDA's view, its tobacco control regulations "may . . . be a better regime[, it] is not the one that Congress established," *MCI Telecomm. Co. v. AT&T*, 512 U.S. 218, 234 (1994), and therefore it cannot stand.

That FDA's regulations purport to be based on a separate law, the FDCA, does not insulate them from the choices Congress made in the tobacco-specific statutes. Congress's legislative judgments are those expressed in all relevant statutes "taken together, as if they were one law." *United States v. Stewart*, 311 U.S. 60, 64 (1940) (citation omitted). Even if the FDCA might once have been interpreted to apply to smokeless tobacco products, that possibility is now foreclosed: "We should be reluctant . . . to read an earlier statute broadly where the result is to circumvent the detailed remedial scheme constructed in a later statute." *Patterson v. McLean Credit Union*, 491 U.S. 164, 181 (1989) (citation omitted).

Moreover, the Government's portrayal of the FCLAA and the CSTHEA as irrelevant to FDA's regulations is contradictory. The "specific respects" in which the tobacco statutes principally "deal with tobacco products," Pet. Br. 44, are the identical "specific respects" in which FDA's regulations, supposedly based on the FDCA, prin-

cipally "deal with tobacco products": advertising and underage tobacco use. By contrast, FDA's regulations do *not* apply to tobacco products the very provisions of the FDCA that make that statute the nation's principal guarantor of the safety and effectiveness of true drugs and medical devices, most prominently, by requiring that drugs and devices be banned if they are not "safe."

Putting aside FDA's incongruous regulations, there is, contrary to the Government's brief, *id.*, an "irreconcilable conflict" between the FDCA and the tobacco-specific statutes. For instance, the CSTHEA provides that "[n]o statement relating to the use of smokeless tobacco products and health, other than the statements required by [the CSTHEA], shall be required by any Federal agency to appear on any package . . . of a smokeless tobacco product." 15 U.S.C. § 4406(a). But drug and device labeling regulations "are a fundamental part of FDA's regulatory scheme." *Zeneca, Inc. v. Shalala*, No. WMN-99-307, 1999 U.S. Dist. LEXIS 12327, at *30 (D. Md. Aug. 11, 1999).

The labeling provisions of the CSTHEA and the FDCA are at war. This is apparent from FDA's attempt to explain why it does not apply to smokeless tobacco products the FDCA's requirement for "adequate warnings against use [of a drug or device] . . . by children where its use may be dangerous to health," § 352(f)(2). *See* 61 Fed. Reg. 44,464-65. The purpose of FDA's tobacco regulations is to reduce tobacco use by children. FDA regards the FCLAA and the CSTHEA as inadequate for this purpose—they "do not amount to a comprehensive scheme . . . they address only a few specific aspects relating to regulation of tobacco products," *id.* at 44,547—and it views tobacco products as "dangerous," *id.* at 44,412. Nevertheless, to rationalize not applying the "adequate warnings" requirement of § 352(f)(2) to

"dangerous" smokeless tobacco (because the CSTHEA precludes FDA from doing so, 15 U.S.C. § 4406(a)), FDA says that the warnings required by the CSTHEA "satisfy this [FDCA] requirement," 61 Fed. Reg. at 44,465. In short, the CSTHEA is *inadequate* to address youth tobacco use, but it provides "*adequate* warnings" under the FDCA "against use . . . by children where [that] use may be dangerous to health." *See id.* (quoting 21 U.S.C. § 352(f)(2)) (emphasis added).

FDA's resort to such illogic with respect to one of the most important provisions of the FDCA, one that relates specifically to the safe use of "drugs" and "devices" by children, demonstrates that the CSTHEA cannot be reconciled with FDA's assertion of jurisdiction over smokeless tobacco products as "drug delivery devices" under the FDCA.

CONCLUSION

For the foregoing reasons, the decision of the court of appeals should be affirmed.

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IN THE
Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, *et al.*,
Petitioners,

v.

BROWN AND WILLIAMSON TOBACCO CORP., *et al.*,
Respondents.

On Writ of Certiorari to the
United States Court of Appeals
for the Fourth Circuit

APPENDIX TO
BRIEF FOR RESPONDENTS
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Public Law 59-384
59th Congress

CHAP. 3915.—An Act For preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That it shall be unlawful for any person to manufacture within any Territory or the District of Columbia any article of food or drug which is adulterated or misbranded, within the meaning of this Act; and any person who shall violate any of the provisions of this section shall be guilty of a misdemeanor, and for each offense shall, upon conviction thereof, be fined not to exceed five hundred dollars or shall be sentenced to one year's imprisonment, or both such fine and imprisonment, in the discretion of the court, and for each subsequent offense and conviction thereof shall be fined not less than one thousand dollars or sentenced to one year's imprisonment, or both such fine and imprisonment, in the discretion of the court.

SEC. 2. That the introduction into any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or from any foreign country, or shipment to any foreign country of any article of food or drugs which is adulterated or misbranded, within the meaning of this Act is hereby prohibited; and any person who shall ship or deliver for shipment from any State or Territory or the District of Columbia to any

other State or Territory or the District of Columbia, or to a foreign country, or who shall receive in any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or foreign country, and having so received, shall deliver, in original unbroken packages, for pay or otherwise, or offer to deliver to any other person, any such article so adulterated or misbranded within the meaning of this Act, or any person who shall sell or offer for sale in the District of Columbia or the Territories of the United States any such adulterated or misbranded foods or drugs, or export or offer to export the same to any foreign country, shall be guilty of a misdemeanor, and for such offense be fined not exceeding two hundred dollars for the first offense, and upon conviction for each subsequent offense not exceeding three hundred dollars or be imprisoned not exceeding one year, or both, in the discretion of the court: *Provided*, That no article shall be deemed misbranded or adulterated within the provisions of this Act when intended for export to any foreign country and prepared or packed according to the specifications or directions of the foreign purchaser when no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which said article is intended to be shipped; but if said article shall be in fact sold or offered for sale for domestic use or consumption, then this proviso shall not exempt said article from the operation of any of the other provisions of this Act.

SEC. 3. That the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce and Labor shall make uniform rules and regulations for carrying out the provisions of this Act, including the collection and examination of specimens of foods and drugs

manufactured or offered for sale in the District of Columbia, or in any Territory of the United States, or which shall be offered for sale in unbroken packages in any State other than that in which they shall have been respectively manufactured or produced, or which shall be received from any foreign country, or intended for shipment to any foreign country, or which may be submitted for examination by the chief health, food, or drug officer of any State, Territory, or the District of Columbia, or at any domestic or foreign port through which such product is offered for interstate commerce, or for export or import between the United States and any foreign port or country.

SEC. 4. That the examinations of specimens of foods and drugs shall be made in the Bureau of Chemistry of the Department of Agriculture, or under the direction and supervision of such Bureau, for the purpose of determining from such examinations whether such articles are adulterated or misbranded within the meaning of this Act; and if it shall appear from any such examination that any of such specimens is adulterated or misbranded within the meaning of this Act, the Secretary of Agriculture shall cause notice thereof to be given to the party from whom such sample was obtained. Any party so notified shall be given an opportunity to be heard, under such rules and regulations as may be prescribed as aforesaid, and if it appears that any of the provisions of this Act have been violated by such party, then the Secretary of Agriculture shall at once certify the facts to the proper United States district attorney, with a copy of the results of the analysis or the examination of such article duly authenticated by the analyst or officer making such examination, under the oath of such officer. After judgment of the court, notice shall be given by publication in such manner as may be prescribed by the rules and regulations aforesaid.

SEC. 5. That it shall be the duty of each district attorney to whom the Secretary of Agriculture shall report any violation of this Act, or to whom any health or food or drug officer or agent of any State, Territory, or the District of Columbia shall present satisfactory evidence of any such violation, to cause appropriate proceedings to be commenced and prosecuted in the proper courts of the United States, without delay, for the enforcement of the penalties as in such case herein provided.

SEC. 6. That the term "drug," as used in this Act, shall include all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals. The term "food," as used herein, shall include all articles used for food, drink, confectionery, or condiment by man or other animals, whether simple, mixed, or compound.

SEC. 7. That for the purposes of this Act an article shall be deemed to be adulterated:

In case of drugs:

First. If, when a drug is sold under or by a name recognized in the United States Pharmacopoeia or National Formulary, it differs from the standard of strength, quality, or purity, as determined by the test laid down in the United States Pharmacopoeia or National Formulary official at the time of investigation: *Provided*, That no drug defined in the United States Pharmacopoeia or National Formulary shall be deemed to be adulterated under this provision if the standard of strength, quality, or purity be plainly stated upon the bottle, box, or other container thereof although the standard may differ from that deter-

mined by the test laid down in the United States Pharmacopoeia or National Formulary.

Second. If its strength or purity fall below the professed standard or quality under which it is sold.

In the case of confectionery:

If it contain terra alba, barytes, talc, chrome, yellow, or other mineral substance or poisonous color or flavor or other ingredient deleterious or detrimental to health or any vinous, malt or spirituous liquor or compound or narcotic drug.

In the case of food:

First. If any substance has been mixed and packed with it so as to reduce or lower or injuriously affect its quality or strength.

Second. If any substance has been substituted wholly or in part for the article.

Third. If any valuable constituent of the article has been wholly or in part abstracted.

Fourth. If it be mixed, colored, powdered, coated, or stained in a manner whereby damage or inferiority is concealed.

Fifth. If it contain any added poisonous or other added deleterious ingredient which may render such article injurious to health: *Provided*, That when in the preparation of food products for shipment they are preserved by any external application applied in such manner that the preservative is necessarily removed mechanically, or by maceration in water, or otherwise, and directions for the removal of said preservative shall be printed on the covering or the package, the provisions of this Act shall be construed as applying only when said products are ready for consumption.

Sixth. If it consists in whole or in part of a filthy, decomposed, or putrid animal or vegetable substance, or any portion of an animal unfit for food, whether manufactured or not, or if it is the product of diseased animal, or one that has died otherwise than by slaughter.

SEC. 8. That the term "misbranded," as used herein, shall apply to all drugs, or articles of food, or articles which enter into the composition of food, the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular, and to any food or drug product which is falsely branded as to the State, Territory, or country in which it is manufactured or produced.

That for the purposes of this Act an article shall also be deemed to be misbranded:

In case of drugs:

First. If it be an imitation of or offered for sale under the name of another article.

Second. If the contents of the package as originally put up shall have been removed, in whole or in part, and other contents shall have been placed in such package, or if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein.

In the case of food:

First. If it be an imitation of or offered for sale under the distinctive name of another article.

Second. If it be labeled or branded so as to deceive or mislead the purchaser, or purport to be a foreign product when not so, or if the contents of the package as originally put up shall have been removed in whole or in part and other contents shall have been placed in such package, or if it fail to bear a statement on the label of the quantity or proportion of any morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any of such substances contained therein.

Third. If in package form, and the contents are stated in terms of weight or measure, they are not plainly and correctly stated on the outside of the package.

Fourth. If the package containing it or its label shall bear any statement, design, or device regarding the ingredients or the substances contained therein, which statement, design, or device shall be false or misleading in any particular: *Provided*, That an article of food which does not contain any added poisonous or deleterious ingredients shall not be deemed to be adulterated or misbranded in the following cases:

First. In the case of mixtures or compounds which may be now or from time to time hereafter known as articles of food, under their own distinctive names, and not an imitation of or offered for sale under the distinctive name of another article, if the name be accompanied on the same label or brand with a statement of the place where said article has been manufactured or produced.

Second. In the case of articles labeled, branded, or tagged so as to plainly indicate that they are compounds, imitations, or blends, and the word "compound," "imitation," or "blend," as the case may be, is plainly stated on the package in which it is offered for sale: *Provided*,

That the term blend as used herein shall be construed to mean a mixture of like substances, not excluding harmless coloring or flavoring ingredients used for the purpose of coloring and flavoring only: *And provided further*, That nothing in this Act shall be construed as requiring or compelling proprietors or manufacturers of proprietary foods which contain no unwholesome added ingredient to disclose their trade formulas, except in so far as the provisions of this Act may require to secure freedom from adulteration or misbranding.

SEC. 9. That no dealer shall be prosecuted under the provisions of this Act when he can establish a guaranty signed by the wholesaler, jobber, manufacturer, or other party residing in the United States, from whom he purchases such articles, to the effect that the same is not adulterated or misbranded within the meaning of this Act, designating it. Said guaranty, to afford protection, shall contain the name and address of the party or parties making the sale of such articles to such dealer, and in such case said party or parties shall be amenable to the prosecutions, fines, and other penalties which would attach, in due course, to the dealer under the provisions of this Act.

SEC. 10. That any article of food, drug, or liquor that is adulterated or misbranded within the meaning of this Act, and is being transported from one State, Territory, District, or insular possession to another for sale, or, having been transported, remains unloaded, unsold, or in original unbroken packages, or if it be sold or offered for sale in the District of Columbia or the Territories, or insular possessions of the United States, or if it be imported from a foreign country for sale, or if it is intended for export to a foreign country, shall be liable to be proceeded against in any district court of the United States within the district where the same is found, and seized for con-

fiscation by a process of libel for condemnation. And if such article is condemned as being adulterated or misbranded, or of a poisonous or deleterious character, within the meaning of this Act, the same shall be disposed of by destruction or sale, as the said court may direct, and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States, but such goods shall not be sold in any jurisdiction contrary to the provisions of this Act or the laws of that jurisdiction: *Provided, however*, That upon the payment of the costs of such libel proceedings and the execution and delivery of a good and sufficient bond to the effect that such articles shall not be sold or otherwise disposed of contrary to the provisions of this Act, or the laws of any State, Territory, District, or insular possession, the court may by order direct that such articles be delivered to the owner thereof. The proceedings of such libel cases shall conform, as near as may be, to the proceedings in admiralty, except that either party may demand trial by jury or any issue of fact joined in any such case, and all such proceedings shall be at the suit of and in the name of the United States.

SEC. 11. The Secretary of the Treasury shall deliver to the Secretary of Agriculture, upon his request from time to time, samples of foods and drugs which are being imported into the United States or offered for import, giving notice thereof to the owner or consignee, who may appear before the Secretary of Agriculture, and have the right to introduce testimony, and if it appear from the examination of such samples that any article of food or drug offered to be imported into the United States is adulterated or misbranded within the meaning of this Act, or is otherwise dangerous to the health of the people of the United States, or is of a kind forbidden entry into, or forbidden to be sold or restricted in sale in the country

in which it is made or from which it is exported, or is otherwise falsely labeled in any respect, the said article shall be refused admission, and the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any goods refused delivery which shall not be exported by the consignee within three months from the date of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe: *Provided*, That the Secretary of the Treasury may deliver to the consignee such goods pending examination and decision in the matter on execution of a penal bond for the amount of the full invoice value of such goods, together with the duty thereon, and on refusal to return such goods for any cause to the custody of the Secretary of the Treasury, when demanded, for the purpose of excluding them from the country, or for any other purpose, said consignee shall forfeit the full amount of the bond: *And provided further*, That all charges for storage, cartage, and labor on goods which are refused admission or delivery shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future importation made by such owner or consignee.

SEC. 12. That the term "Territory" as used in this Act shall include the insular possessions of the United States. The word "person" as used in this Act shall be construed to import both the plural and the singular, as the case demands, and shall include corporations, companies, societies and associations. When construing and enforcing the provision of this Act, the act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation, company, society, or association, within the scope of his employment or office, shall in every case be also deemed to be the act, omission, or failure of such

corporation, company, society, or association as well as that of the person.

SEC. 13. That this Act shall be in force and effect from and after the first day of January, nineteen hundred and seven.

Approved, June 30, 1906.

AN ACT

To prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

CHAPTER I—SHORT TITLE

SECTION 1. This Act may be cited as the Federal Food, Drug, and Cosmetic Act.

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

(a) The term "Territory" means any Territory or possession of the United States, including the District of Columbia and excluding the Canal Zone.

(b) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term "Department" means the Department of Agriculture of the United States.

(d) The term "Secretary" means the Secretary of Agriculture.

(e) The term "person" includes individual, partnership, corporation, and association.

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g) The term "drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories.

(h) The term "device" (except when used in paragraph (n) of this section and in sections 301 (i), 403 (f), 502 (c), and 602 (c)) means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(j) The term "official compendium" means the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any

article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(l) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

(o) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(p) The term "new drug" means—

(1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug the composition of which is such that such drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or mis-

branded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 404 or 505.

(e) The refusal to permit access to or copying of any record as required by section 703.

(f) The refusal to permit entry or inspection as authorized by section 704.

(g) The manufacture within any Territory of any food, drug, device, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 303 (c) (2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303 (c) (3), which guaranty or undertaking is false.

(i) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 404, 406 (b), 504, or 604.

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 505, or 704 concerning any method or process which as a trade secret is entitled to protection.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done which such article is held for sale after shipment in interstate commerce and results in such article being misbranded.

(l) The using, on the labeling of any drug or in any advertising relating to such drug, of any representation or suggestion that an application with respect to such drug is effective under section 505, or that such drug complies with the provisions of such section.

INJUNCTION PROCEEDINGS

SEC. 302. (a) The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, and subject to the provisions of section 17 (relating to notice to opposite party) of the Act entitled "An Act to supplement existing laws against unlawful restraints and monopolies, and for other purposes", approved October 15, 1914, as amended (U. S. C., 1934 ed., title 28, sec. 381), to restrain violations of section 301, except paragraphs (e), (f), (h), (i), and (j).

(b) In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this Act, trial shall be by the court, or, upon demand of the accused, by a jury. Such trial shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of section 22 of such Act of October 15, 1914, as amended (U.S.C., 1934 ed., title 28, sec. 387).

PENALTIES

SEC. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than \$1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than \$10,000, or both such imprisonment and fine.

(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 301, with intent to defraud or mislead, the penalty shall be imprisonment for not more than three years, or a fine of not more than \$10,000, or both such imprisonment and fine.

(c) No person shall be subject to the penalties of subsection (a) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301 (a), that such article is not adulterated or misbranded, within the meaning of

this Act, designating this Act, or to the effect, in case of an alleged violation of section 301 (d), that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce; or (3) for having violated section 301 (a), where the violation exists because the article is adulterated by reason of containing a coal-tar color not from a batch certified in accordance with regulations promulgated by the Secretary under this Act, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the coal-tar color, to the effect that such color was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this Act.

SEIZURE

SEC. 304. (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce, or which may not, under the provisions of section 404 or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: *Provided, however,* That no libel for condemnation shall be instituted under this Act, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply (1) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this Act, or (2)

when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.

(b) The article shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall confirm, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so

made within a reasonable time, the claimant may apply to the court of one such jurisdiction, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

(c) The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, his attorney or agent, to obtain a representative sample of the article seized, and as regards fresh fruits or fresh vegetables, a true copy of the analysis on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyzed were obtained.

(d) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this Act or the laws of the jurisdiction in which sold: *Provided*, That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this Act or the laws of any State or Territory in which sold, the

court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Act under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond. Any article condemned by reason of its being an article which may not, under section 404 or 505, be introduced into interstate commerce, shall be disposed of by destruction.

(e) When a decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the article.

(f) In the case of removal for trial of any case as provided by subsection (a) or (b)—

(1) The clerk of the court from which removal is made shall promptly transmit to the court in which the case is to be tried all records in the case necessary in order that such court may exercise jurisdiction.

(2) The court to which such case was removed shall have the powers and be subject to the duties, for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

HEARING BEFORE REPORT OF CRIMINAL VIOLATION

SEC. 305. Before any violation of this Act is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom

such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

REPORT OF MINOR VIOLATIONS

SEC. 306. Nothing in this Act shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this Act whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

PROCEEDINGS IN NAME OF UNITED STATES; PROVISION AS TO SUBPENAS

SEC. 307. All such proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States. Notwithstanding the provisions of section 876 of the Revised Statutes, subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any such proceeding.

CHAPTER IV—FOOD

DEFINITIONS AND STANDARDS FOR FOOD

SEC. 401. Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: *Provided*, That no definition and standard of identity and no standard of quality shall be established for fresh

or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocados, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Secretary for avocados, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

ADULTERATED FOOD

SEC. 402. A food shall be deemed to be adulterated—

(a)(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared,

packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(b)(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406: *Provided*, That this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this Act and such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this Act for the purposes of coloring citrus fruit.

(d) If it is confectionery, and it bears or contains any alcohol or nonnutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 per centum, natural gum, and pectin: *Provided*, That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts,

or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.

MISBRANDED FOOD

SEC. 403. A food shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If it is offered for sale under the name of another food.

(c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(f) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) If it purports to be or is represented as—

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 401, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 401, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

(i) If it is not subject to the provisions of paragraph (g) of this section unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each: *Provided*, That, to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in de-

ception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: *Provided*, That to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream.

EMERGENCY PERMIT CONTROL

SEC. 404. (a) Whenever the Secretary finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with micro-organisms during the manufacture, processing, or packaging thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he then, and in such case only, shall promulgate regulations providing for the issuance, to manufacturers, processors, or packers of such class of food in such locality, of permits to which shall be attached such conditions governing the manufacture, processing, or packing of such class of food, for such temporary period of time, as may be necessary to protect the public health; and after the effective date of such regulations, and during

such temporary period, no person shall introduce or deliver for introduction into interstate commerce any such food manufactured, processed, or packed by any such manufacturer, processor, or packer unless such manufacturer, processor, or packer holds a permit issued by the Secretary as provided by such regulations.

(b) The Secretary is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for the reinstatement of such permit, and the Secretary shall, immediately after prompt hearing and an inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.

(c) Any officer or employee duly designated by the Secretary shall have access to any factory or establishment, the operator of which holds a permit from the Secretary, for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator.

REGULATIONS MAKING EXEMPTIONS

SEC. 405. The Secretary shall promulgate regulations exempting from any labeling requirements of this Act (1) small open containers of fresh fruits and fresh vegetables and (2) food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on con-

dition that such food is not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

TOLERANCES FOR POISONOUS INGREDIENTS IN FOOD AND CERTIFICATION OF COAL-TAR COLORS FOR FOOD

SEC. 406. (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 402(a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402 (a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents.

CHAPTER V—DRUGS AND DEVICES

ADULTERATED DRUGS AND DEVICES

SEC. 501. A drug or device shall be deemed to be adulterated—

(a)(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if it is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 504.

(b) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescrib-

ing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

(c) If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(d) If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

MISBRANDED DRUGS AND DEVICES

SEC. 502. A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight,

measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha eucaïne, barbituric acid, betaeucaïne, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulphonmethane; or any chemical derivative of such substance, which derivative has been by the Secretary, after investigation, found to be, and by regulations designated as, habit forming; unless its label bears the name, quantity, and percentage of such substance or derivative and in juxtaposition therewith the statement "Warning—May be habit forming".

(e) If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including, whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine,

Senate floor and in House hearings. 144 Cong. Rec. S5001 through *id.* at S6481 (daily eds. May 18 through June 17, 1998) (S. 1415, 105th Cong. (1988)) (the "McCain Bill," as modified and printed in the Cong. Rec., 144 Cong. Rec. at S. 5034-84 (daily ed. May 19, 1998)); *The Tobacco Settlement (Parts 1-3): Hearings Before the Subcomm. on Health and Environment of the House Comm. on Commerce*, 105th Cong. (1997-98). The President's 1999 State of the Union Address called for such legislation in the current Congress. 145 Cong. Rec. H260 (daily ed. Jan. 19, 1999). Thus, whether to grant FDA jurisdiction over tobacco products remains before Congress.²⁵ Since 1996, fifteen bills have been introduced to grant FDA such jurisdiction.²⁶ Each of these bills would have granted FDA jurisdiction either by creating a new

²⁵ The Government contends that the entire history of Congress' consideration and rejection of bills to give FDA jurisdiction over tobacco products is no more meaningful than Congress' inaction since FDA asserted jurisdiction. Pet. Br. at 42-43. To the contrary, Congress' "failure" to enact bills to overturn FDA's recent assertion of jurisdiction is easily understood given the immediate judicial challenge to that assertion, the district court's stay of FDA's regulations except for the youth access provisions, the subsequent appellate ruling and this Court's grant of certiorari. Moreover, in 1997, Congress expressly disavowed any intent to affect this case when it provided funding for those FDA regulations not stayed by the district court: "The [Senate] Committee [on Appropriations] is aware of the ongoing litigation. . . . *The Committee emphasizes that its action is in no way to be construed as concurring or disagreeing with any court ruling regarding FDA's authority . . .*" S. Rep. No. 105-51, 105th Cong. 117 (1997) (emphasis added); see also S. Rep. No. 105-212, 105th Cong. 124 (1998) (same for FY '99); S. Rep. No. 106-80, 106th Cong. 127 (1999) (same for FY '00). Properly, the Government does not seek to draw any inference from the appropriation. See *TVA v. Hill*, 437 U.S. 153, 190 (1978).

²⁶ S. 527, S. 1414, S. 1415, S. 1492, H.R. 762, H.R. 1244, H.R. 3028 (all 105th Cong. (1997)); S. 1530, S. 1638, S. 1648, S. 1889, H.R. 3474, H.R. 3738, H.R. 3868, H.R. 3889 (all 105th Cong. (1998)).

regulatory scheme exclusively for tobacco products or by modifying the FDCA's standards for safety and effectiveness. *None* of these bills accepted FDA's view that the FDCA, as it stands, fits tobacco products. Rather, these bills reflect the Members' continued understanding that application of the FDCA to tobacco products would require a ban.

Congress has amended the FDCA 57 times in the past 60 years, but has never granted FDA jurisdiction over tobacco products.²⁷ If Congress had wanted to confer such jurisdiction on FDA, it would have said so by now. Even when interpreting a public health protection statute, as is the FDCA, "we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." 62 *Cases . . . of Jam v. United States*, 340 U.S. 593, 600 (1951).

II. THE RELEVANT STATUTES AND THEIR HISTORY DEMONSTRATE THAT FDA LACKS JURISDICTION OVER TOBACCO PRODUCTS.

Both FDA's general assertion of authority and its tobacco regulations are incompatible with Congress' tobacco-specific legislation. The *only* way that the FDCA can be reconciled with the FCLAA, the CSTHEA, and the ADAMHA Amendments is to conclude that the FDCA does not cover tobacco products. In this context, statutes such as these should "be taken together, as if they were one law." *United States v. Stewart*, 311 U.S. 60, 64 (1940); *Hubbard v. United States*, 514 U.S. 695, 701 (1995). FDA's demand that this Court resolve this case exclusively on the basis of FDA's expansive reading of the definitions in the FDCA is, therefore, legally indefensible.

²⁷ See Walsh, Federal Food, Drug, and Cosmetic Act with Amendments iii-iv (amendments through 1980); 21 U.S.C. § 301 Historical & Statutory Notes 33-34 (West Supp. 1998) (amendments since 1980).

The classic judicial task of reconciling many laws enacted over time, and getting them to "make sense" in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute.

United States v. Fausto, 484 U.S. 439, 453 (1988). Thus, the "proper inquiry is how best to harmonize", *United States v. Estate of Romani*, 118 S. Ct. 1478, 1486 (1998), the FDCA with the tobacco-specific legislation.

It is well settled that subsequently enacted and more specific statutes (like the tobacco-specific statutes) prevail over earlier and more general statutes (like the FDCA). Such later and more specific statutes preclude efforts to "extend the reach of the earlier Act's vague language to the limits which, read literally, the words might permit." *NLRB v. Drivers, Chauffeurs, Helpers, Local Union No. 639*, 362 U.S. 274, 291-92 (1960). Not only do "precisely targeted" statutes prevail over the more general when there are "numerous other regulations and statutes littering" the field, but a general statute should not be expanded "so dramatically as to make many other pieces misfits." *United States v. Sun-Diamond Growers of California*, 119 S. Ct. 1402, 1410 (1999).²⁸

²⁸ The Government cites *TVA v. Hill*, 437 U.S. at 189-90, for the proposition that an "implied repeal occurs only when there is an irreconcilable conflict between the old and the new laws," and asserts that there is no "irreconcilable conflict" between Congress' tobacco-specific statutes "and the conclusion that tobacco products fall within the reach of the Act." Pet. Br. at 44. Respondents do not argue that any portion of the FDCA has been implicitly repealed by Congress' tobacco-specific statutes. Rather, the argument is that those statutes preclude FDA's novel construction of the FDCA. Thus, the standards for an implied repeal are irrelevant. See *Argentine Republic v. Amerasia Shipping Corp.*, 488 U.S. 428, 438 (1989) (rejecting implied repeal argument and noting that passage by Congress of a later statute precludes an expansive construction of an earlier statute). In any event, there

The regulatory program established by Congress' tobacco-specific statutes, premised on the absence of FDA jurisdiction, reflects a political compromise that carefully balances economic interests, personal freedom, and principles of federalism with public health and other interests, including the need to reduce youth access to tobacco. This compromise marks the place where "opposing social and political forces have come to rest." *Chrysler Corp. v. Brown*, 441 U.S. 281, 313 (1979). FDA regulation of tobacco products is fundamentally at odds with Congress' program and would shatter that political balance.

A. FDA's Claim of Authority to Regulate Tobacco Products Is Incompatible with the Federal Cigarette Labeling and Advertising Act.

FDA's claim of authority over tobacco products cannot be reconciled with the policy and regulatory program Congress established in the FCLAA. In statutory text, the FCLAA announces:

It is the policy of the Congress, and the purpose of this chapter, to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby—

- (1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and
- (2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and ad-

are numerous irreconcilable conflicts between FDA's assertion of jurisdiction and Congress' tobacco-specific statutes.

vertising regulations with respect to any relationship between smoking and health.

15 U.S.C. § 1331.

The Government improperly recharacterizes these purposes as simply seeking to avoid "diverse, nonuniform, and confusing cigarette labeling and advertising regulations." Pet. Br. at 45 (quoting FCLAA § 1331(2)(B)). This contention ignores the far broader purposes reflected in the other paragraphs of § 1331 and the operative provisions of the FCLAA. These include maintaining the primacy of Congress in establishing national policy with respect to smoking and health, and protecting commerce and the national economy consistent with the policy of informing consumers about the health risks associated with cigarettes. Congress' purpose to protect commerce while informing consumers, *codified at* § 1331(2)(A), necessarily precludes any federal agency from banning cigarettes.

Even FDA acknowledges that it lacks the statutory tools and the expertise to take account of these economic and political factors.²⁹ FDA is not authorized to protect "commerce and the national economy." Its role is limited to carrying out the mandate of its governing statute—a mandate that requires it to ban any drug or device not found to be both "safe" and "effective." See 21 U.S.C. §§ 355 (d)-(e), 360c(a)(2)(A)-(C), 360e(d)-(e). However, safety is one of several elements in Congress' complex political balance. Indeed, Congress determined in 1970 that cigarettes are "dangerous," Pub. L. No. 91-222, § 4, 84 Stat. 87 (1970), and accordingly, has prescribed specific warnings, 15 U.S.C. § 1333, but rejected a ban.

²⁹ "FDA medical officers should not be considering economic issues as part of their safety and efficacy reviews. . . . Although some people look to FDA to resolve those difficult dilemmas, FDA does not have the expertise to decide them." FDA Comm'r Kessler, *Remarks at the Symposium on Pharmacoeconomics* (Oct. 22, 1993).

The very grounds used by FDA to justify its attempt to regulate tobacco products without banning them— notwithstanding its finding that they are unsafe—show how far the Agency has overreached. FDA explains that the health care system could be "overwhelmed" by the need to treat addicted smokers if tobacco products were banned, and that in these circumstances "a black market and smuggling would develop to supply smokers." 61 Fed. Reg. 44,396, 44,413 (1996). But FDA has no expertise with respect to these issues—and no authority under the FDCA to consider them.³⁰

Lacking suitable authority, FDA has sought to invent its own tobacco law to avoid a head-on collision with Congress' tobacco-specific statutes.³¹ The court of appeals properly recognized this "transparent action by the FDA [as] obvious sophistry," taken "to attain its end, not the end contemplated by Congress." *Brown & Williamson*, Pet. App. at 24a, 30a. Notwithstanding FDA's inventions, a principled application of the FDCA would create numerous irreconcilable conflicts with the FCLAA:

³⁰ FDA's efforts to address "unique problems of medical judgment, law enforcement and public policy . . . cannot justify a federal agency of specifically delimited jurisdiction from implementing equally unique control solutions not authorized by Congress." *American Pharm. Ass'n v. Weinberger*, 377 F. Supp. 824, 831 (D.D.C. 1974), *aff'd sub nom. American Pharm. Ass'n v. Mathews*, 530 F.2d 1054 (D.C. Cir. 1976) (per curiam) (FDA's methadone distribution regulations "must be first passed upon by Congress").

³¹ FDA's construction of the FDCA and the tobacco-specific statutes reads out of them their legislatively established "intelligible principle[s]," *J.W. Hampton Jr., & Co. v. United States*, 276 U.S. 394, 404-410 (1928) (Taft, C. J.): tobacco products are not immediately banned under the FDCA even though found "unsafe," nor regulated as Congress intended under the tobacco-specific statutes. FDA therefore would lack any congressional direction regarding how to regulate tobacco products. "A construction of the statute that avoids this kind of open-ended grant should certainly be favored." *Industrial Union Dep't, AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 646 (1979) (plurality opinion).

Authority to Ban. As the court of appeals recognized: "A faithful application of the statutory language would lead to a ban on tobacco products—a result not intended by Congress." *Id.* at 29a.³² Under the FDCA, a drug or device is "misbranded" and may not be sold if it is "dangerous to health when used in the dosage or manner, . . . recommended, or suggested in the labeling thereof." 21 U.S.C. § 352(j). Yet FDA has found that cigarettes, when used in the recommended manner (*i.e.*, smoked), are "dangerous to health," 61 Fed. Reg. 44,396, 44,412 (1996), and are "the single leading cause of preventable death in the United States." *Id.* at 44,398. Thus, if the FDCA actually applied to tobacco products, they would have to be banned.³³

³² To bolster its argument that FDA may ban tobacco products, the Government conflates two issues: the preemptive effect of the FCLAA on state law; and the preclusive effect of the FCLAA on federal agencies. Pet. Br. at 45. But substantially different legal standards govern these separate issues, in part, due to the "strong presumption" against preemption, *Cipollone*, 505 U.S. at 523, "consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety." *Medtronic*, 518 U.S. at 485. *Cipollone* concerned the preemptive effect on state law of 15 U.S.C. § 1334. *Cipollone*, 505 U.S. at 517. Unlike *Cipollone*, this case involves the preclusive effect of the FCLAA on a federal agency; it cannot be decided by only reading § 1334.

³³ FDA's position is that tobacco products are "devices" that deliver the "drug" nicotine. But if FDA finds that there is a reasonable probability that a device will cause serious adverse health consequences, it "shall issue an order requiring the appropriate person . . . to immediately cease distribution of the device." 21 U.S.C. § 360h(e)(1). Moreover, any drug that is not "generally recognized" as safe may not be marketed unless FDA approves the drug as having been shown to be safe. 21 U.S.C. §§ 321(p), 355(b), 331(d). The Director of FDA's Center for Drug Evaluation and Research has noted that "for a drug that's going to be sold over-the-counter . . . there has to be a very high certainty that the drug is very safe." Woodcock, *When Is a Medical Product Too*

But banning tobacco products is manifestly inconsistent with Congress' intent. Congress has repeatedly refused to give FDA jurisdiction over tobacco products precisely *because* it would lead to a ban. Congress has never delegated that decision to any administrative agency—and certainly not to FDA, whose repeated denials of such authority were a predicate for Congress' own legislative program.

Labeling Authority. The FCLAA and the CSTHEA expressly preclude FDA or any other agency from requiring any statement on tobacco product labeling with respect to tobacco and health except as prescribed by Congress. 15 U.S.C. §§ 1334(a), 4406(a).³⁴ Yet regulation of product labeling is a core feature of FDA authority over "drugs" and "devices." *See generally*, 21 U.S.C. § 352. Indeed, the FDCA explicitly requires health warnings on drugs and devices. For example, a "drug" or "device" is "misbranded" if its labeling does not include "adequate warnings against use . . . by children where its use may be dangerous to health." 21 U.S.C. § 352(f)(2). Given that FDA called the use of tobacco products a "pediatric disease," 61 Fed. Reg. 44,396, 45,238 (1996), and concluded that tobacco products are "dangerous", *id.* at 44,412, FDA *must* require such warnings if tobacco products are "drugs" or "devices." But it is precluded from doing so by the FCLAA and the CSTHEA. To avoid the conflict without acknowledging it, FDA announced that the current congressionally-prescribed warn-

Risky? An Interview with FDA's Top Drug Official, FDA Consumer, The Magazine of the U.S. Food and Drug Administration, Sept.-Oct. 1999, at 10 ("FDA Consumer (Sept.-Oct. 1999)").

³⁴ Nothing in *Banzhaf v. FCC*, 405 F.2d 1082 (D.C. Cir. 1968), suggests the contrary. *Banzhaf* concerned regulation of broadcasters—not cigarette manufacturers—and did not require statements on tobacco product packages concerning smoking and health.

ings satisfy the FDCA. *Id.* at 44,465. But if FDA genuinely believed those warnings were truly “adequate,” its regulations would be unnecessary.

Further, under the FDCA, a “drug” or “device” is misbranded unless its labeling contains “adequate directions” for safe use. 21 U.S.C. § 352(f)(1); 21 C.F.R. §§ 201.5, 801.5. Given FDA’s findings, no such directions could possibly be written for tobacco products. But, even if such directions were possible, FDA could not require them consistent with the FCLAA because they would be in addition to the congressionally-prescribed warnings.

Finally, FDA’s tobacco-product regulations would require all product packages to carry the health-based “intended use” statement: “Nicotine Delivery Device for Persons 18 or Older.” 21 C.F.R. §§ 897.25, 897.32(c). To seek to avoid a conflict with the FCLAA and the CSTHEA labeling preclusions, FDA contends that this warning about nicotine is somehow unrelated to “smoking and health.” 61 Fed. Reg. 44,396, 44,544 (1996). But the very basis of FDA’s rulemaking is the health effects of nicotine “delivery” by tobacco products.

Package Inserts. FDA also claims authority to require that package inserts “contain health information and information about the chemicals added to cigarettes and smokeless tobacco.” 61 Fed. Reg. 44,396, 44,465 (1996). FDA argues that the FCLAA does not preclude such package inserts because inserts would be “in”—not “on”—cigarette packages. *Id.* FDA was forced to adopt this absurd view of FCLAA preclusion given its desire to assert jurisdiction over tobacco products.

Ingredients. Congress determined that the health effects of cigarette ingredients are to be evaluated by HHS and reported to Congress. 15 U.S.C. § 1335a. Nevertheless, under FDA’s regulation of tobacco products as “devices,”

FDA would evaluate—and sometimes could prescribe—their ingredients, *see* 21 U.S.C. §§ 360d(a)(2)(A), 360, 360e(c)(1)(B), thus usurping Congress’ authority.

Moreover, the FCLAA mandates that cigarette manufacturers disclose to HHS the identity of all cigarette ingredients, which HHS must treat “as trade secret or confidential information,” 15 U.S.C. § 1335a(b)(2)(A), and store “in a locked cabinet or file.” *Id.* at § 1335a(b)(1)(C). By contrast, under the FDCA, a drug is misbranded unless its label includes “the established name and quantity . . . of each active ingredient” as well as “the established name of each inactive ingredient” 21 U.S.C. § 352(e)(1)(A)(ii, iii). In fact, FDA claims authority “to require labeling or listing of other substances present or delivered by cigarettes.” 61 Fed. Reg. 44,396, 44,463 (1996). However, such requirement would result in the public disclosure of the very information that Congress protected from disclosure.

In sum, it is impossible to harmonize FDA’s asserted authority over tobacco products with the regulatory program in the FCLAA. Rather, the court of appeals found that FDA has sought “to maneuver around the obstacles created by the operative provisions of the” FDCA, *Brown & Williamson*, Pet. App. at 29a; and “[c]ongressional policy . . . cannot be harmonized with the FDA’s assertion of jurisdiction over tobacco products.” *Id.* at 44a. This disharmony permits only one conclusion: Congress has not granted FDA such authority.

B. FDA’s Assertion of Federal Control over Retail Sales Conflicts With Congress’ Legislation to Foster and Support Restrictions on Youth Access to Tobacco Products at the State Level.

FDA’s one-size-fits-all program conflicts with the purpose of the ADAMHA Amendments, which contemplate

varying approaches from one State to another. Indeed, the FDCA preempts the States from imposing "requirements" that are different from or in addition to FDA's. See 21 U.S.C. § 350k. Thus, if the FDCA applies to tobacco products, Section 360k would prohibit the States from establishing any youth-access restrictions and enforcement procedures that differ from FDA's regulations, even if those restrictions were specifically designed to fit local circumstances.³⁵ FDA's regulations would thus wrest the lead enforcement role from the States contrary to Congress' intent. 21 C.F.R. § 897.14. The regulations also transform every improper sale of a tobacco product by a local merchant into a federal offense, see 21 U.S.C. §§ 331(a), 333(f)(3); 21 C.F.R. § 897.1(b), expanding the scope of federal criminal jurisdiction without congressional authorization.

III. FDA MAY NOT SEIZE AUTHORITY OVER TOBACCO PRODUCTS FROM CONGRESS.

As the court of appeals observed: "At its core, this case is about who has the power to make this type of major policy decision." *Brown & Williamson*, Pet. App. at 53a.³⁶ Congress has repeatedly enacted tobacco-specific legislation to address the health risks associated with tobacco products—including those relied upon by FDA as the basis of its asserted jurisdiction. In so doing, Congress answered the "who" question, and established a policy *against* FDA jurisdiction. As the D.C. Circuit stated in *ASH v. Harris*, "[i]f the [FDCA] requires ex-

³⁵ FDA, in its discretion, may waive the FDCA preemption. But in triggering that authority, FDA has shifted primary authority from the States (and Congress) to itself.

³⁶ FDA recently recognized its inability to modify the fundamental policy underlying the FDCA: If there is "more that can be done" beyond "enforcing the standards and approach called for in our statute," to achieve a "a balance [that is] correct according to society," "[t]hat's really a general consensus rather than our call." FDA Consumer (Sept.-Oct. 1999) at 11.

pansion [to cover cigarettes], that is the job of Congress." *ASH*, 635 F.2d at 243. The court of appeals agreed that "this type of decision involving countervailing national policy concerns is just the type of decision left for Congress." *Brown & Williamson*, Pet. App. at 22a.

As we have shown, Congress did not intend to grant FDA authority over tobacco products when it enacted the FDCA. For over 60 years, FDA denied that it had such authority until it reversed course in its 1995-1996 rule-making.³⁷ FDA communicated its lack of jurisdiction to Congress repeatedly, forcefully and authoritatively—in testimony and official correspondence from senior Agency officials and their Cabinet-level superiors.

FDA's conduct was consistent with its statements. Immediately after the 1964 Surgeon General's Report, the FTC proposed a rule to require health warnings in cigarette advertising. See 29 Fed. Reg. 530 (1964). FDA did nothing. Nor did it respond to *any* of the Surgeon General's numerous subsequent reports on tobacco and health. It knew it had no jurisdiction. In such circumstances, both "established practice" and "the want of assertion of power by those who presumably would be alert to exercise it" are "significant in determining whether such power was actually conferred." *BankAmerica Corp. v. United States*, 462 U.S. 122, 131 (1983).

Congress understood and concurred with FDA's view that the FDCA does not extend to tobacco products. See *United States v. Rutherford*, 442 U.S. 544, 554 n.10 (1979) (legislative intent "correctly discerned" when Congress was aware of FDA interpretation and did not "alter

³⁷ Contrary to the Government's contention, FDA's prior position was not based on an absence of sufficient evidence regarding the "intended use" of tobacco products. Pet. Br. at 43. Rather, FDA asserted that, as a matter of law and congressional intent, it lacked authority over tobacco products absent health claims. See, e.g., Novitch Letter, Jt. App. at 54, 67; see also *id.* at 47.

that interpretation although it . . . amended the statute").³⁸ Further, Congress repeatedly declined to pass legislation to grant FDA jurisdiction over tobacco products. "Congress' failure to act on the bills proposed on this subject provides added support for concluding that Congress acquiesced in the [agency's] rulings." *Bob Jones Univ. v. United States*, 461 U.S. 574, 601 (1983).

[A] refusal by Congress to overrule an agency's construction of legislation is at least some evidence of the reasonableness of that construction, particularly where the administrative construction has been brought to Congress' attention through legislation specifically designed to supplant it.

United States v. Riverside Bayview Homes, Inc., 474 U.S. 121, 137 (1985).

The evidence of Congress' awareness of, and failure to overturn, FDA's longstanding interpretation, is far more compelling than the evidence in previous cases where this Court relied upon such facts. Here, the unenacted bills are unusually numerous (36) and span nearly 70 years (1929-1998), and thus reflect consistent congressional understanding of, and acquiescence in, the existing state of the law over a very long period.³⁹ Just last year, the

³⁸ The Government argues that *Motor Vehicle Mfrs. Ass'n v. State Farm*, 463 U.S. 29 (1983), precludes effective congressional ratification of FDA's longstanding statutory interpretation. Pet. Br. at 43. *State Farm*, however, involved an agency's policy judgment on a matter delegated to it to decide, not its interpretation of a statute. *State Farm* held only the former immune to congressional ratification, 463 U.S. at 45, not the latter.

³⁹ The Government notes that congressional will is expressed through enacted legislation, not unenacted bills. Pet. Br. at 42. Respondents agree. However, the purpose and meaning of the statutes Congress did enact, the FDCA, the FCLAA, the CSTHEA, and the ADAMHA Amendments, as well as Congress' intent in enacting those statutes, are brightly illuminated by the competing alternatives before Congress. In a further effort to avoid the force of this

Senate debated for three weeks the merits of comprehensive tobacco legislation, including extensive provisions which would have established FDA regulatory authority, and similar legislation was considered by the House Committee on Commerce.

Indeed, Congress' recognition that FDA lacks authority was a predicate for Congress' tobacco-specific legislation. Congress "believed that it was filling a regulatory void," *International Bhd. of Teamsters v. Daniel*, 439 U.S. 551, 570 (1979), when it created its tobacco-specific statutes, a belief which the FDA "actively encouraged." *Id.* The enactment of legislation that "implicitly recognizes" the construction of a statute is "persuasive of legislative recognition" that the "construction is the correct one." *Apex Hosiery Co. v. Leader*, 310 U.S. 469, 488-489 (1940); see also *United States v. American Trucking Ass'n*, 310 U.S. 534, 550 (1940). Now that Congress has installed a statutory regime for tobacco, it is far too late for FDA to conjure up a contrary interpretation of its jurisdiction. *Cf. Morton v. Ruiz*, 415 U.S. 199, 237 (1974) ("too late now" for agency to change interpretation after it consistently "led Congress to believe that interpretation"); *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 289 (1974) (agency "not now free" to change its interpretation of statute).

Thus, Congress ratified FDA's prior construction of the FDCA when it enacted the FCLAA. In reserving to itself the authority to regulate tobacco products, and in constructing its own comprehensive regulatory scheme for

history, the Government asserts that "[c]ongressional inaction also 'lacks persuasive significance because several equally tenable inferences may be drawn from such action, including the inference that the existing legislation already incorporated the offered change.'" *Id.* The historical evidence here shows that any such inference is untenable: Congress plainly understood that FDA lacked authority to regulate tobacco products.

such products, Congress relied upon its own conclusion—buttressed by FDA's statements—that FDA lacked authority over tobacco products and would not take any action to negate or undermine Congress' specific enactments. Congress' tobacco-specific statutes therefore preclude FDA's new construction of the FDCA. *See CFTC v. Schor*, 478 U.S. 833, 846 (1986) (finding ratification "virtually conclusive" when "Congress has not just kept its silence by refusing to overturn the administrative construction, but has ratified it with positive legislation. . ."); *see also* Eskridge, *Interpreting Legislative Inaction*, 87 Mich L. Rev. 67, 110-11 (1988) (finding the strongest case for presuming correctness of a prior agency statutory interpretation is a "building block interpretation," *i.e.*, "an authoritative settled interpretation . . . upon which public decisionmakers have (apparently) relied in developing further legal rules").

Simply put, FDA has appropriated Congress' constitutional authority to make major national policy. This Court has been especially skeptical of administrative interpretations that would forge new, major policies that must be resolved by Congress:

Reviewing courts are not obliged to stand aside and rubberstamp . . . administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute. Such review is always properly within the judicial province, and the courts would abdicate their responsibility if they did not fully review such administrative decisions. . . . [Where the review is] of a judgment as to the proper balance to be struck between competing interests, "[t]he deference owed to an expert [agency] cannot be allowed to slip into a judicial inertia which results in the unauthorized assumption by an agency of major policy decisions properly made by Congress."

NLRB v. Brown, 380 U.S. 278, 291-2 (1965) (quoting *American Ship Bldg. Co. v. NLRB*, 380 U.S. 300, 318 (1965)) (emphasis added); *see also* *BATF v. FLRA*, 464 U.S. 89, 97 (1983).

Here, "the thread between these regulations and any grant of authority by the Congress is so strained that it would do violence to established principles of separation of powers," *Chrysler Corp. v. Brown*, 441 U.S. at 307-308, to credit FDA's assertion of jurisdiction "with the 'binding effect of law.'" *Id.* at 308.

CONCLUSION

Accordingly, the Court should affirm the judgment of the court of appeals.

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IN THE
Supreme Court of the United States

FOOD and DRUG ADMINISTRATION, *et al.*,
v. *Petitioners,*

BROWN and WILLIAMSON TOBACCO CORP., *et al.*,
Respondents.

On Writ of Certiorari to the
United States Court of Appeals
for the Fourth Circuit

BRIEF FOR RESPONDENTS
NATIONAL ASSOCIATION OF CONVENIENCE STORES
AND ACME RETAIL, INC.

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QUESTION PRESENTED

Whether Congress granted jurisdiction to the Food and Drug Administration to regulate the retail sale of tobacco products under the medical device provisions of the Federal Food, Drug, and Cosmetic Act, even though Congress expressly proscribed any regulation inconsistent with state autonomy preserved by the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act.

RULE 29.6 LISTING

There is no parent or subsidiary company to be listed pursuant to Rule 29.6.

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IN THE
Supreme Court of the United States

No. 98-1152

FOOD and DRUG ADMINISTRATION, *et al.*,
v. *Petitioners,*

BROWN and WILLIAMSON TOBACCO CORP., *et al.*,
Respondents.

On Writ of Certiorari to the
United States Court of Appeals
for the Fourth Circuit

BRIEF FOR RESPONDENTS
NATIONAL ASSOCIATION OF CONVENIENCE STORES
AND ACME RETAIL, INC.

OPINIONS BELOW

The opinions below are identified in Brief for Petitioners (Pet. Br.) 1.

JURISDICTION

The basis for this Court's jurisdiction is set forth at Pet. Br. 1.

STATUTORY AND REGULATORY
PROVISIONS INVOLVED

The Brief for Petitioners fails to list among the statutes involved the ADAMHA Reorganization Act.

STATEMENT

From the time tobacco products were first marketed in this country, their retail sale has been regulated by the States (and local governments), and not by the national government. Congress, in 1992, recognized and expressly preserved local autonomy over tobacco retailing in the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act (the "ADAMHA Amendments").

In 1996, claiming jurisdiction under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the Secretary of Health and Human Services ("HHS") and the Commissioner of Food and Drugs declared the end of state autonomy in tobacco-access control by promulgating regulations prescribing how cigarettes and smokeless tobacco could be distributed and sold throughout the United States. 61 Fed. Reg. 44,396 (1996). These regulations, to be enforced by the Food and Drug Administration ("FDA"), prohibit the sale of cigarettes and smokeless tobacco to those under age 18, and require retailers to check identification of persons under age 27, 21 C.F.R. § 897.14(a)-(b) (1999); prohibit vending machine sales except in adult-only establishments, *id.* § 897.16(c)(2) (ii); prohibit self-service displays of tobacco products, *id.* § 897.16(c)(1); and prohibit the provision of free samples to any person, *id.* § 897.16(d).

The regulations extend FDA's enforcement responsibilities to over 500,000 retail establishments throughout the United States. 61 Fed. Reg. 44,578. Retailers of tobacco products, including 68,000 outlets operated by members of respondent, National Association of Convenience Stores, must redesign and reconstruct their stores to comply with the regulations. 61 Fed. Reg. 44,589. Every failure to conform to FDA's mandate is a federal offense, 21 C.F.R.

§ 897.1(b); 21 U.S.C. §§ 331(b), (k), punishable by federal prosecution, *id.* § 333(a)(1), or by civil penalty imposed by FDA and reviewable in the federal courts of appeals, *id.* § 333(f). Respondents brought suit challenging FDA's assertion of jurisdiction under the FDCA.

SUMMARY OF ARGUMENT

Historically, state and local governments decided how to regulate the retail sale of tobacco in the United States. Such laws have ranged from complete bans (since repealed) on cigarette sales at the turn of the century to restrictions on sales to minors, self-service displays, vending machines, or free samples (which continue to the present). Against this backdrop, in July 1992, Congress passed, and the President signed, the ADAMHA Amendments, Pub. L. No. 102-321, 106 Stat. 323 (1992), the most recent expression of congressional intent concerning tobacco-access regulation. The ADAMHA Amendments promise Substance Abuse Prevention and Treatment ("SAPT") block grants to States that have laws prohibiting the sale of tobacco products to individuals under age 18 and that enforce those laws effectively. 42 U.S.C. § 300x-26 (1994).

Congress, by enacting the ADAMHA Amendments, confirmed that the States should continue to enact and enforce tobacco-access restrictions, and recognized that restrictive measures appropriate for one State or locality to reach the goal of preventing underage tobacco purchases may not be right for another. The policy Congress embraced in the Amendments was not one of uniform federal regulation; rather, Congress decided to preserve and enhance the States' role in regulating access to tobacco by leaving to each State the decision as to what legislation is needed, and by rewarding with block grants those States that enforce their laws effectively.

The States and localities responded to Congress' policy. They have implemented varied regulatory approaches depending upon what restriction, or combination of restrictions, best meets the needs of the particular State or locale. One may ban cigarette vending machines outright, whereas another may impose location, line-of-sight, or lockout device requirements. In some jurisdictions penalties apply to underage purchasers, whereas in others law enforcement targets only tobacco sellers. Some States restrict free samples, coupons, or rebate offers; others do not. By enforcing these laws to achieve the tobacco-access reductions contemplated under the Amendments, every State, so far, has qualified for the full SAPT block grant promised by Congress.

Four years after Congress decided to support state authority and encourage local regulation of retail tobacco sales, FDA effectively reversed that decision. FDA's uniform regulations preempt or nullify hundreds of state and local laws, many of which the States enacted at the behest of Congress. Moreover, FDA's regulations impermissibly impose upon the States, retroactively, additional obligations that Congress did not intend when enacting the ADAMHA Amendments. FDA's regulations contradict Congress' decision about *who* should regulate access to tobacco by minors and *how* it should be done.

FDA's regime of uniform tobacco-access standards replace the legislative and enforcement flexibility that Congress determined the States should retain. Indeed, the regulatory system Congress chose is fundamentally contrary to the federal command-and-control regulatory system FDA has imposed.

Congress never granted FDA power to supplant the state-by-state regulatory system Congress had chosen; basic principles of administrative law prohibit a federal agency

from promulgating regulations that conflict with statutory directives. In this case the conflict is clear. Congress, moreover, has expressly declared that any HHS rule or regulation "inconsistent" with the ADAMHA Amendments "shall not have any legal effect[.]" Pub. L. No. 102-321, sec. 203, § 1954(b), 106 Stat. 410. For these reasons,¹ FDA's assertion of jurisdiction, and its resulting tobacco regulations, should be struck down.

ARGUMENT

I. CONGRESS EXPLICITLY PRESERVED STATE LEGISLATIVE AND ENFORCEMENT FLEXIBILITY.

A. The ADAMHA Amendments Rely Exclusively Upon States To Attain Federal Tobacco-Access-Reduction Goals.

Controversy over the consumption of tobacco predates the founding of the republic.² For over a hundred years, concern about public health has led state and local governments to exercise their authority to police the retail sale of tobacco within their own borders. For example, during the late 1800's and early 1900's, 14 States passed, though they later repealed, complete bans on the sale of cigarettes.³ Throughout this century, States have restricted

¹ Respondents on this brief agree with, and hereby rely on, the arguments made in the briefs of the other respondents.

² Jacob Sullum, *For Your Own Good: The Anti-Smoking Crusade and the Tyranny of Public Health* 15-23 (1998) (describing centuries of debate over tobacco).

³ 1907 Ark. Acts 280; 1921 Ark. Acts 490; 1921 Idaho Sess. Laws 185; 1921 Idaho Sess. Laws 262; 1905 Ind. Acts 52; 1909 Ind. Acts 28; 1896 Iowa Acts 96; 1921 Iowa Acts 203; 1909 Kan. Sess. Laws 257; 1927 Kan. Sess. Laws 171; 1909 Minn. Laws 194; 1913 Minn. Laws 580; 1905 Neb. Laws 198; 1919 Neb. Laws 180; 1895 N.D. Laws 32; 1925 N.D. Laws 106; 1901 Okla. Sess. Laws 13; 1915

the legal purchase age for tobacco products.⁴ Local governments have long regulated access to tobacco products,⁵ and continue to do so today, *see pp. 15-17, infra*.

Okla. Sess. Laws 190; 1909 S.D. Laws 142; 1917 S.D. Laws 153; 1897 Tenn. Pub. Acts 30; 1921 Tenn. Pub. Acts 5; 1921 Utah Laws 145; 1925 Utah Laws 68; 1909 Wash. Laws 249; 1911 Wash. Laws 133; 1905 Wis. Laws 82; 1915 Wis. Laws 139. *See Austin v. Tennessee*, 179 U.S. 343 (1900) (upholding 1897 statute banning cigarettes sales); *see also* Rivka Widerman, *Tobacco Is A Dirty Weed. Have We Ever Liked It? A Look At Nineteenth Century Anti-Cigarette Legislation*, 38 Loy. L. Rev. 387, 423 (1992) (concluding that the primary purpose of the earliest anti-cigarette legislation was to protect young people).

⁴ 1890 Ala. Acts 785; Comp. Laws of Alaska § 4967 (1933); 1921 Ariz. Sess. Laws Ch. 63 § 1; 1929 Ark. Acts 152; 1891 Cal. Stats. 70; 1891 Colo. Sess. Laws 131; Conn. Gen. Stat. § 6283 (1930); 19 Del. Laws 783 (1894); 26 D.C. Stat. 736 (1929); 1907 Fla. Laws ch. 5716; 1889 Ga. Laws 149; 1890 Haw. Sess. Laws 62; 1921 Idaho Sess. Laws 185; 1907 Ill. Laws 265; 1913 Ind. Act 643; Iowa Code § 1553 (1935); 1933 Kan. Sess. Laws 122; 1914 Ky. Acts 104; 1900 La. Acts 98; 1909 Me. Laws 123; 1914 Md. Laws 835; 1886 Mass. Acts 72; 1909 Mich. Pub. Acts 226; 1913 Minn. Laws 580; Miss. Code Ann. § 819 (1930); 1909 Mo. Laws 447; 1895 Mont. Laws 542; 1885 Neb. Laws 105; Nev. Comp. Laws § 10184 (1929); 1885 N.H. Laws 60; 1904 N.J. Laws 163; 1901 N.M. Laws 3; 1897 N.Y. Laws 256; 1891 N.C. Sess. Laws 276; 1925 N.D. Laws 26; Ohio Code Ann. § 12965 (Banks-Baldwin 1936); 1917 Okla. Sess. Laws 148; 1893 Or. Laws 86; 1901 Pa. Laws 323; 1896 R.I. Pub. Laws 281; S.C. Code § 255(19) (1932); 1917 S.D. Laws 153; 1921 Tenn. Pub. Acts 5; 1899 Tex. Gen. Laws 237; Utah Rev. Stat. § 93-1-12 (1933); 1937 Vt. Laws 213; 1889-90 Va. Laws 213; 1895 Wash. Laws 126; W. Va. Code Ann. Ch. 150 § 20e (Barnes 1923); 1891 Wis. Laws 434; 1895 Wyo. Sess. Laws 46.

⁵ *See Gundling v. City of Chicago*, 177 U.S. 183, 187-88 (1900) ("Whether dealing in and selling cigarettes is that kind of a business which ought to be licensed is, we think, considering the character of the article sold, a question for the state, and through it, for the city, to determine for itself, and that an ordinance providing reasonable conditions upon the performance of which a

At the federal level, Congress has repeatedly considered legislation addressing who should regulate tobacco marketing and promotion, and how they should do so. An extensive body of statutory law has emerged from those deliberations and embodies Congress' intent.⁶ The last expression of congressional intent on this subject, which came in the ADAMHA Amendments of 1992, dealt with access regulation. An examination of the text, history, and constitutional basis of this law confirms that FDA lacks authority to regulate tobacco products under the FDCA.

Congress relied upon and preserved the States' authority to control youth access when it passed the ADAMHA Amendments, which established financial incentives for States to regulate access successfully. Under the Amendments, a State can qualify for a full allotment of block-grant funds if it agrees to four conditions:

- (1) To have in effect a law prohibiting every manufacturer, retailer, or distributor of tobacco products from selling or distributing them to anyone under age 18 [section 300x-26(a)(1)];
- (2) To enforce access restrictions "in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18" [section 300x-26(b)(1)];
- (3) To conduct annual, random, unannounced inspections to measure and ensure compliance [section 300x-26(b)(2)(A)];

licensee may be granted to sell such article does not violate any provision of the Federal Constitution").

⁶ The Brief for Respondents Philip Morris Incorporated and Lorillard Tobacco Company describes these statutes.

- (4) To submit an annual report to the Secretary of HHS describing its enforcement activities, its success in reducing tobacco access to those underage, and its strategies for enforcing its access laws in the coming year [section 300x-26(b)(2)(B)].

This program thus encourages States to enact and enforce their own tobacco-access laws. States and localities have responded exactly as Congress desired by adding measures of varying design and approach to the large body of access restrictions already on the books. *See* Addendum to Supplemental Brief of Plaintiffs-Appellees National Association of Convenience Stores and Acme Retail, Inc., in the United States Court of Appeals for the Fourth Circuit ("Addendum") (six volumes) (June 27, 1997).

Congress made clear that the federal regulatory policy was to be found in the Amendments, and was not to be altered by HHS. Specifically, section 203(a) of the ADAMHA Amendments added to the Public Health Service Act new section 1954(b), which provides in pertinent part as follows:

(b) **FEDERAL ACCOUNTABILITY.**—Any rule or regulation of the Department of Health and Human Services that is inconsistent with the amendments made by this Act shall not have any legal effect. . . .

106 Stat. 410.

B. Congress Rejected All Proposals to Grant HHS Any Authority to Regulate Tobacco Access.

The legislative history of the ADAMHA Amendments confirms that Congress intended to leave the States in control of tobacco-access policy. The Amendments originated in the House Committee on Energy and Commerce.

That Committee rejected proposed language for the ADAMHA Amendments that would have undermined the States' historical role in deciding how best to regulate underage access to tobacco. On November 1, 1991, Rep. Henry Waxman, Chairman of the Committee's Subcommittee on Health and the Environment, introduced the Community Mental Health and Substance Abuse Services Improvement Act of 1991, which would have revised and extended services for mental health and substance abuse administered by the Alcohol, Drug Abuse, and Mental Health Administration ("ADAMHA") and created new incentives for States to reduce tobacco sales to those under age 18. H.R. 3698, 102d Cong. (1991). When the bill was in the Energy and Commerce Committee, Rep. Waxman offered an amendment that would have withheld grant funds unless States enacted specific access restrictions strikingly similar to those FDA promulgated in its final tobacco regulations. *See* Amendment to the Committee Print of November 15, 1991 (H.R. 3698, as Reported From the Subcommittee on Health and the Environment) (Nov. 19, 1991). Rep. Waxman's proposed amendment would have deprived a State of its block grant unless the State required that tobacco vending machines be locked, controlled, or located where persons under 18 could not enter without a parent or guardian. *Id.* at 2-3. This is the kind of specific tobacco-access restriction FDA now seeks to impose as federal law and enforce throughout the United States.⁷

On March 24, 1992, however, the Commerce Committee reported the bill without Rep. Waxman's proposal.

⁷ FDA's regulations ban the use of vending machines unless "located in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time." 21 C.F.R. § 897.16(c)(2)(ii).

See H.R. 3698, 102d Cong. (1992). On the House floor, Rep. Bliley, Ranking Minority Member of the Subcommittee and the Committee, explained that the underlying policy of H.R. 3698 was to avoid any measure that "reduces the flexibility of States to address the critical needs of their populations," for such a measure "takes the initiative away from local people who have the best grasp of their local environments and shifts it to Federal bureaucrats." 138 Cong. Rec. 6622 (1992).

Undeterred, Rep. Waxman pressed his proposal one more time, in the House-Senate conference on the legislation. Rep. Bliley later described why the Conference Committee rejected it:

Again, Rep. Waxman's staff was attempting to interject proposals to broaden the Secretary's authority beyond the scope agreed to by a majority of the Subcommittee. For this reason, the proposal was rejected by the negotiators.

Comment of Rep. Thomas A. Bliley 3 (Oct. 25, 1993) (responding to HHS's Notice of proposed regulations implementing 42 U.S.C. § 300x-26, 58 Fed. Reg. 45,156 (1993)) ("Bliley Comment").⁸ Rep. Waxman's proposal offered a more detailed, federally controlled program for restricting underage access to tobacco; that program was rejected. In considering and then rejecting it, the conferees from the House and the Senate held fast to the policy that

⁸ The Bliley Comment also described Rep. Waxman's initial effort to broaden the Secretary's authority: the original bill had provoked "strong objections to granting the Secretary 'significant' discretionary powers that were so broad that HHS could establish any guidelines for enforcement while insisting on compliance under the threat of a loss of funds[.]" and "[i]t was generally agreed that such an enforcement scheme went beyond the establishment of a minimum age requirement and would usurp state flexibility in determining reasonable enforcement mechanisms." Bliley Comment 2.

States continue to be free to design tobacco-access restrictions unhindered by the dictates of the federal bureaucracy. This policy became the Act of Congress.

C. HHS Recognized Congressional Intent to Preserve State Autonomy.

HHS recognized congressional intent in 1996 when it promulgated rules to implement the ADAMHA Amendments. Initially, to be sure, HHS had contemplated an active role for itself in shaping state legislative and enforcement efforts. It proposed a requirement that States put in place "well-designed procedures" to ensure compliance with state access laws setting the minimum age at 18. 58 Fed. Reg. 45,156, 45,173 (1993) (proposed 45 C.F.R. § 96.130(c)(2)). Examples included vending machine restrictions and licensing requirements. *Id.* This proposal provoked comments that HHS was deviating from Congress' intent: "Many commenters" informed HHS that the requirement that States adopt particular "well-designed procedures" exceeded "the scope of the statute, congressional intent and Department discretion under the statute." 61 Fed. Reg. 1492, 1495 (1996).

After considering the comments, HHS adopted final regulations that reflected the force of these criticisms. 61 Fed. Reg. 1508 (codified at 45 C.F.R. §§ 96.123, 96.130). In describing its final regulations, HHS repeatedly emphasized the importance of the States' flexibility in determining the design of their own access restrictions, *id.* at 1493-96, and eliminated the requirement for "well-designed procedures," *id.* at 1495. For example, HHS stated:

Bans and restrictions on vending machines and locking devices are viable options for States to consider in reducing tobacco sales to minors, but again,

under this regulation the Department intends to allow States flexibility in the strategies they use to enforce tobacco control laws.

Id. at 1496. Similarly, HHS considered and rejected suggestions that it require other specific enforcement mechanisms, including banning self-service displays and sampling. *Id.* at 1500-01. When reminded of congressional intent that it preserve state autonomy, HHS declined to impose its will on the States.

II. FDA'S REGULATIONS USURP STATE AUTHORITY PRESERVED BY CONGRESS.

A. FDA's Exercise of Jurisdiction Repudiates Congress and Its Plan to Control Tobacco Access by Minors.

At the very outset of its tobacco rulemaking, by contrast, FDA questioned the balance struck by Congress in the ADAMHA Amendments, and argued that only direct federal involvement would achieve the reduction in tobacco access that Congress believed could be achieved through the ADAMHA Amendments. FDA noted that, pursuant to the Amendments, the Substance Abuse and Mental Health Services Administration ("SAMHSA") had "proposed a program of State-operated enforcement activities that would restrict the sale or distribution of tobacco products to individuals under 18 years of age." 60 Fed. Reg. 41,314, 41,362 (1995).⁹ FDA voiced its support for the "basic objectives" of this program mandated by Congress, but it was FDA's view that the "full achievement" of Congress' objectives demanded "a broad arsenal of controls"—namely, FDA's proposed regulations. *Id.*

⁹ The Amendments, enacted in 1992, established SAMHSA as an agency of the Public Health Service within HHS. 42 U.S.C. § 290aa(a).

In the preamble to its final tobacco regulations, FDA went even further: it "disagreed that regulation of tobacco sales or decisions about eligibility and maturity are traditional State functions[.]" and it omitted any description of the historical background of state regulation, which Congress intended to preserve. *See* 61 Fed. Reg. 44,396, 44,429 (1996). Thus, after Congress chose state autonomy instead of federal command and control for regulating tobacco access, FDA imposed a program of nationally uniform tobacco-access regulations that conflicts directly with congressional intent as expressed in the ADAMHA Amendments.¹⁰

FDA's rule broadens significantly the scope of its enforcement responsibilities. By its own count, FDA's regulations cover over 500,000 retail establishments throughout the United States. 61 Fed. Reg. 44,578. Every failure to conform to FDA's mandate is a federal offense, 21 C.F.R. § 897.1(b); 21 U.S.C. §§ 331(b), (k), punishable by federal prosecution, *id.* § 333(a)(1), or by civil penalty imposed by FDA and reviewable in the federal courts of appeals, *id.* § 333(f). If FDA's enforce-

¹⁰ FDA also disagreed with its parent agency's view that the ADAMHA Amendments are adequate to achieve their purpose. HHS had stated that the flexible approach agreed upon by Congress should work: "Eliminating virtually all sales to minors does not even present particularly difficult enforcement problems. It simply requires workable procedures [by the States] which create swift and sure sanctions for violations, with minimal cost or inconvenience to retailers and adult customers." 58 Fed. Reg. 45,165. HHS had estimated that the program under the ADAMHA Amendments could reduce sales of cigarettes to persons under age 18 as much as two-thirds within three years. *Id.* at 45,158. That estimate was published before FDA decided to regulate tobacco products. HHS reduced its estimate after FDA announced its tobacco regulations, when it became expedient for HHS to support the asserted need for, and predicted benefit of, FDA's competing program. *See* 61 Fed. Reg. 1501-02.

ment history is any guide, it is only a matter of time before corner stores contesting civil penalties appear in federal courts across the land. *Cf. United States v. Park*, 421 U.S. 658, 665-66 (1975) (five-count conviction for food adulteration in violation of the FDCA, fine of \$50 for each count).

B. FDA's Regulations Preempt State Statutes and Local Ordinances.

In the exercise of their traditional police powers, state and local governments have adopted a wide variety of tobacco-access restrictions, none of which has ever been disturbed by any federal tobacco-specific statute. The FDCA, however, preempts every state or local enactment that addresses the subject matter of FDA's regulations with respect to a device, if that enactment differs from or adds to the regulations:

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device. . . .

21 U.S.C. § 360k(a)(1). Under this section, FDA requirements do not establish thresholds that States are free to exceed or constraints that States are free to relax. Rather, the preemption section of the FDCA reflects Congress' unequivocal grant of plenary regulatory control over medical devices to FDA.

FDA concedes that its regulations preempt outright a variety of state and local tobacco-access laws—including statutes requiring a higher age of eligibility for purchasing tobacco products, as well as ordinances imposing tougher restrictions on self-service displays, vending machines, or

identification requirements. 61 Fed. Reg. 44,548-49. FDA contends, however, that "only a limited number of State and local requirements are preempted and even those may qualify for exemption from preemption under [21 U.S.C. § 360k(b)]." *Id.* at 44,548. The reality is that FDA's regulations automatically preempt hundreds of state and local tobacco-access laws. Among the laws are the following:

1. *Age Requirements.* Alabama, Alaska, and Utah prohibit the sale of cigarettes to anyone under age 19, Addendum, Vol. 1, Tab 1, in contrast to FDA's regulations, which set the age at 18. 21 C.F.R. § 897.14(a); 61 Fed. Reg. 44,396 (providing compliance date of Feb. 28, 1997). In the fall of 1996, the three States sought exemptions from preemption. *See* 62 Fed. Reg. 7390, 7391-94 (1997) (Docket No. 96N-0249). FDA agreed the laws were preempted and granted the exemptions effective December 29, 1997, more than a year after the States had applied for them. 62 Fed. Reg. 63,271, 63,274 (1997) (codified at 21 C.F.R. §§ 808.51, 808.52, 808.94). Thus, from February 28, 1997 until December 29, 1997, FDA preempted statutes in Alabama, Alaska, and Utah, and thereby *lowered* the legal tobacco-purchasing age in those States from 19 to 18.

2. *Absolute Bans on Vending Machines and Self-Service Displays.* At least 177 local ordinances completely ban tobacco sales from vending machines or self-service displays, or both. *See* Addendum, Vols. 1-3, Tab 2. FDA's regulations allow vending machines and self-service displays in adult-only venues. *See* 21 C.F.R. § 897.16(c)(2)(ii). FDA's regulations preempt¹¹ these

¹¹ More properly, "will preempt," if the district court's stay is dissolved. Two provisions of FDA's tobacco regulations became effective on February 28, 1997—the age restriction and the pur-

ordinances and revive marketing methods these governments had prohibited.

3. *Location Restrictions on Vending Machines and Self-Service Displays.* At least 17 local ordinances restrict the location of vending machines or self-service displays, or both, within adult-only venues. *See* Addendum, Vol. 4, Tab 3. FDA's regulations impose no location restrictions within such venues. *See* 21 C.F.R. § 897.16(c)(2)(ii). FDA's regulations preempt these ordinances and relax controls that these localities adopted.

4. *Age Verification Requirements.* At least one state statute and one local ordinance require that retailers verify age with a government-issued identification card. *See* Addendum, Vol. 4, Tab 4. FDA's regulations do not require a government-issued identification card. *See* 21 C.F.R. § 897.14(b)(1).¹² FDA's regulations preempt these requirements and dilute the proof-of-age standard in these jurisdictions.

In addition to preempting state or local laws that prohibit too much, FDA's tobacco regulations preempt or nullify laws that embody different, competing solutions. Approaches to access restriction that States and localities may no longer employ include the following:

5. *Lockout Devices on Vending Machines and Self-Service Displays.* At least 17 localities require that vending machines or self-service displays, or both, be equipped

with age-verification requirement. 21 C.F.R. § 897.14(a)-(b). Although the district court stayed regulations that had not gone into effect at the time of its ruling in April, 1997, it permitted the continued implementation of the provisions that had taken effect. Appendix To Petition For a Writ of Certiorari ("Pet. App.") 135a.

¹² FDA stated that "the final rule does not require . . . a Federal, State, or local government identification card." 61 Fed. Reg. 44,438-39.

with lockout devices controlled by the retailer. *See* Addendum, Vol. 4, Tab 5. FDA's regulations restrict vending machines and self-service displays to adult-only venues. 21 C.F.R. § 897.16(c)(2)(ii). FDA's regulations preempt or nullify these localities' determinations that lockout devices adequately control access to tobacco products from vending machines and self-service displays.

6. *Line-of-Sight Restrictions for Vending Machines and Self-Service Displays.* At least five States and 35 localities require that vending machines or self-service displays, or both, be placed in the line of sight of employees in retail establishments. *See* Addendum, Vol. 5, Tab. 6. FDA's regulations restrict vending machines and self-service displays to adult-only venues. FDA's regulations preempt or nullify these localities' determinations that line-of-sight restrictions are an effective way to control access to tobacco products from vending machines and self-service displays.

7. *Sampling Restrictions.* At least 48 States prohibit the provision of free samples of tobacco products to minors, but not to adults; and several localities restrict where sampling can be done. *See* Addendum, Vol. 6, Tab 7. FDA's complete prohibition on free samples, 21 C.F.R. § 897.16(d), preempts or nullifies these state laws.

So far, state and local governments have filed over 300 applications with FDA seeking exemptions from preemption. *See* Index to Docket No. 96N-0249 listing applications (Aug. 31, 1999). The continued viability of these laws now depends on whatever dispensations may result from future FDA rulemakings.

C. There is Inherent Conflict Between the ADAMHA Amendments and FDA's Assertion of Jurisdiction Over Tobacco Products.

By enacting the ADAMHA Amendments, Congress acknowledged that States and local governments are the proper source of tobacco-access restrictions. Congress did not offer States the choice of regulating retailers according to federal standards or having state law preempted by federal regulation. Nor did it enact a detailed regulatory scheme of its own, around which the States might legislate. Nor did it pass legislation preempting any state law that regulates retail access to tobacco products. Rather, Congress encouraged the States to establish age 18 as the legal age for purchasing tobacco products, and encouraged the States to enforce their own legislation in a manner of their choosing. It remained the responsibility of the States to reduce minors' ability to buy tobacco products. FDA's "broad arsenal of controls" now stands as an obstacle to the accomplishment of Congress' purposes in enacting the ADAMHA Amendments.

The Government insists there is no "inherent or irreconcilable conflict" between the ADAMHA Amendments and FDA's assertion of jurisdiction over tobacco products under the FDCA, because States can seek permission from FDA to enforce their otherwise preempted laws. Pet. Br. 48. But as the court of appeals found, "the possibility of a discretionary exemption does not take away the inherent conflict[.]" Pet. App. 51a. That States are forced to petition¹³ FDA to spare congressionally induced legislation, and then await the outcome of another FDA rule-making, demonstrates the severity of this conflict.

The jurisdictional grant asserted by the Secretary of HHS and the Commissioner of Food and Drugs pursuant

¹³ 21 C.F.R. §§ 808.1, *et seq.*

to the FDCA is incompatible with the tobacco-access control plan Congress enacted in the ADAMHA Amendments. In the provisions of the Amendments dealing specifically with tobacco, Congress refused to disturb state authority and discretion to determine how best to achieve the goal of tobacco-access reduction. The Government's argument, Pet. Br. 48, that the ADAMHA Amendments do not protect all state regulations of tobacco misses the point that the Amendments were intended to preserve the States' autonomy to regulate tobacco access. FDA has promulgated a rule that takes that autonomy away.

The Administrative Procedure Act ("APA") provides that a reviewing court "shall hold unlawful and set aside agency action . . . found to be in excess of statutory jurisdiction, authority, or limitations, or short of statutory right[.]" 5 U.S.C. § 706(2)(C). The inherent inconsistency between the two competing programs is apparent from a plain reading of the operative provisions of the ADAMHA Amendments and the FDA regulations.

Congress, however, did not leave the resolution of such inconsistencies to the general provisions of the APA. In drafting the ADAMHA Amendments, Congress went out of its way expressly to preclude the adoption of administrative regulations that would conflict with its legislative policy:

Any rule or regulation of the Department of Health and Human Services that is inconsistent with the amendments made by this Act shall not have any legal effect. . . .

106 Stat. 410. This provision expresses a congressional determination that the basic policy set forth in the ADAMHA Amendments shall be the only federal policy relating to the retail sale of tobacco products, and that the substantive restrictions on retail sales to per-

sons under age 18 shall be designed and enforced by the States. The Amendments make clear the limits of federal jurisdiction over retail sales of tobacco. Congress left no room for an agency within HHS to disagree. FDA's assumption of authority to decide which state and local restrictions will survive, and which will not, should be rejected.

III. FDA's REGULATIONS IMPERMISSIBLY IMPOSE FUNDING CONDITIONS NOT APPROVED BY CONGRESS.

That FDA is usurping jurisdiction in an area Congress left to the States becomes even more evident when the ADAMHA Amendments are considered in light of their constitutional basis—the spending power in Article I, § 8, cl. 1. The Amendments condition the availability of federal funds on the States taking certain actions. There is no doubt that Congress, under its spending power, may condition the receipt of federal funds on certain state action. *King v. Smith*, 392 U.S. 309, 333 n.34 (1968). Congress, however, must make these conditions explicit and unambiguous, so that States understand the bargain they have made when they accept the terms of the “contract.” *Pennhurst State School & Hospital v. Halderman*, 451 U.S. 1, 17 (1981). Once the conditions have been set, and the States have accepted those terms, a federal agency does not have the authority to alter the obligations that States must undertake in order to receive the funds. This Court has held:

Though Congress' power to legislate under the spending power is broad, it does not include surprising participating States with post acceptance or “retroactive” conditions.

Id. at 25; see also *King*, 392 U.S. at 333 n.34 (HEW cannot approve a change in conditions “inconsistent with the controlling federal statute”).

The ADAMHA Amendments offered the States an incentive to reduce the sales of tobacco products to individuals under age 18. The Amendments made the conditions of that offer explicit and unambiguous. So far, every State has accepted those conditions and qualified for the full SAPT block grant promised by Congress.¹⁴

FDA's regulations impermissibly impose on the States further obligations that burden the administration of their programs and interfere with their ability to meet their goals and obtain their promised share of funding under the Amendments. A State must now seek permission from FDA to do what Congress induced it to do, and must bear the risk that FDA will delay or deny its dispensation. For example, numerous local governments have determined that too many underage sales result from vending machines.¹⁵ As a result, city councils passed ordinances banning outright the sale of tobacco products in vending machines. See p. 15, *supra*. But under FDA's regulations, a local government's new vending-machine law cannot be enforced: it is preempted because it is different from FDA's vending-machine regulation, which permits vending machines “in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time.” 21 C.R.F. § 897.16

¹⁴ SAMHSA reported to Congress that “[a]ll States are in material compliance with the [ADAMHA Amendments]. They have laws prohibiting the sale or distribution of tobacco to minors, and they are enforcing those laws All States expect to achieve the goal of a maximum sales-to-minors rate of 20 percent by Federal Fiscal Year (FFY) 2003.” SAMHSA, *Synar Regulation Implementation FY 97 State Compliance 1* (undated).

¹⁵ In a “model law,” HHS recommended the States adopt a measure prohibiting tobacco sales through vending machines, presumably because HHS also thought such a prohibition would be effective. 58 Fed. Reg. 45,165 (Section 5(b) of the Model Sale of Tobacco Products to Minors Control Act).

(c)(2)(ii). State and local governments must apply to FDA for an exemption, and, in the interim, either select another approach that will achieve the necessary reduction in tobacco sales to minors or put its SAPT block grant at risk.

The experience of Alaska illustrates the damage that FDCA preemption can do when applied to state access-restriction programs. In its exemption application filed with FDA in the fall of 1996, Alaska voiced its "great concern" with the higher percentage of its high school students who became frequent cigarette smokers compared with the general U.S. high school population, and stated that restricting sales to purchasers 19 years and older "severely limit[ed] legal access of cigarettes to high school students." State of Alaska's Application for Exemption from 21 C.F.R. § 897.14(a) (Docket No. 96N-0249) (Nov. 27, 1996) 2, 3.¹⁶ Alaska insisted that restriction "must continue to remain an overall part of the state's tobacco use deterrent efforts." *Id.* at 4. Nonetheless, for 10 months, FDA took it away (and took it away from Alabama and Utah). *See* p. 15, *supra*. Depriving States of their preferred approaches to access reduction is not a result Congress intended when it passed the ADAMHA Amendments. Forcing States to choose other approaches, or to risk the loss of ADAMHA Amendment funds, is prohibited by *Pennhurst*.

¹⁶ That Alaska and other States believe a higher minimum age sales law is an effective means to reduce cigarette consumption among adolescents could not have surprised HHS, for it recommended that States adopt a measure setting the age for tobacco sales at 19. 58 Fed. Reg. 45,165 (Section 5(a) of the Model Sale of Tobacco Products to Minors Control Act).

CONCLUSION

Accordingly, the Court should affirm the judgment of the court of appeals.

Respectfully submitted,

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In the Supreme Court of the United States

**FOOD AND DRUG ADMINISTRATION, ET AL.,
PETITIONERS**

v.

BROWN AND WILLIAMSON TOBACCO CORP., ET AL.

**ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT**

REPLY BRIEF FOR THE PETITIONERS

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REPLY BRIEF FOR THE PETITIONERS

Respondents do not challenge here the findings that led FDA to conclude that the nicotine in tobacco products is intended to affect the structure or function of the body. In particular, respondents do not dispute that (1) the nicotine in tobacco products is highly addictive and acts as a sedative, stimulant, and appetite suppressant, (2) consumers use tobacco products predominantly for those purposes, (3) manufacturers have known for years that consumers use their products predominantly to obtain nicotine's pharmacological effects, (4) manufacturers have privately referred to nicotine as a drug and cigarettes as devices for delivering that drug, and (5) they have long engineered their products to deliver to consumers the precise doses of nicotine they need to obtain its powerful effects. Gov't Br. 3-8. The sole question presented therefore is whether, given those unchallenged findings, tobacco products are drug-delivery devices within the meaning of the FDCA. As we show in our opening brief, FDA reasonably concluded that they are.

A. Structure/Function Definitions

1. a. Respondents contend (RJR Br. 11-13) that a product falls within the structure/function definitions only if a manufacturer makes a structure/function "claim." The term "claim," however, does not appear in the definitions. Instead, those definitions encompass as "drugs" and "devices" products that are "intended" to affect the structure or function of the body, 21 U.S.C. 321(g)(1)(C) and (h)(3), and "intended" simply does not mean the same thing as "claimed." The dictionary definition of "intend" is "to have in mind as a design or purpose." *Webster's Third New International Dictionary* 1175 (1986). The Court long ago stated that "[t]he law presumes that every man intends the legitimate consequence[s] of his own acts," *Agnew v. United States*, 165 U.S. 36, 53 (1897), and more recently, it interpreted "primarily intended for use" in an analogous statutory context as "the item's likely use." *Posters 'N' Things Ltd. v. United States*, 511

U.S. 513, 521 (1994). In contrast, the definition of "claim" is "an assertion, statement, or implication (as of value, effectiveness, qualification, eligibility)." *Webster's Third* at 414. Where a provision of the FDCA is meant to turn on such representations, it specifically so provides. Gov't Br. 26.

Because manufacturers ordinarily have a financial incentive to make claims about a product so that customers will be induced to buy it, the claims that are made in connection with a sale *usually* reflect a product's "intended" effects. In some cases, however, manufacturers can count on consumers to understand the uses and pharmacological effects of a product, and to buy it for those reasons, even in the absence of any claims by the manufacturers. In such cases, FDA is not powerless to protect the public health. It may treat those products as drugs or devices when it finds, based on all the objective evidence, that the pharmacological effects of the product are "intended." That is the situation here: The evidence convincingly shows that the nicotine in tobacco products is intended to be used by consumers to sustain addiction and for sedation, stimulation, and weight control. It would be contrary to the fundamental public health purposes of the Act to conclude that a product is altogether excluded from regulation (even to prevent its adulteration or to improve its safety) precisely *because* its drug-like attributes are so widely known and thoroughly embedded in the behavior of consumers and manufacturers as to render claims to that effect superfluous. Gov't Br. 25.

Even respondents shrink from that consequence of their position, for they concede that FDA could regulate a product such as Prozac if it were sold only by its name, without any representations about its uses or pharmacological effects. Respondents would reach that result, however, on the theory that the product name has taken on a "secondary meaning" that constitutes an "implied claim" about the product's uses and effects, attributes they say tobacco products do not have. RJR Br. 15; B&W Br. 24-25. We disagree that tobacco

products do not have similar attributes. But there is no need to resort to concepts such as "secondary meaning" or "implied claim" (which do not appear in the Act) to ensure that a product marketed simply as Prozac is covered by the FDCA. The reason the Act applies in that example is that consumers would be aware of the uses and effects of the product based on its name alone, they would buy and use the product accordingly, and manufacturers could count on them to do so. The same is true for tobacco products.

Respondents' claims-only theory threatens to open a gaping hole in the Act's protection of the public health. Under respondents' theory, manufacturers of potent drugs could escape regulation by marketing their products with the same chemical name as a brand name product, but without accompanying drug claims. A manufacturer could freely market in that manner such drugs as "fluoxetine" (the chemical name for the compound in Prozac) and "sildenafil citrate" (the chemical name for the compound in Viagra), and FDA would be unable to assure their safety or effectiveness.¹

b. Respondents' claims-only interpretation also conflicts with FDA's "intended use" regulations, which have been in effect since 1952. See Gov't Br. 26-27 & n.5. Those regulations, which are entitled to deference under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), and are not challenged here, provide that "intended use" refers to the "objective intent" of the person legally responsible for the labeling, not to that person's "claims." 21 C.F.R. 201.128 (drug), 801.4 (device). The regulations do provide that a manufacturer's "labeling claims"

¹ Respondents concede (RJR Br. 15) that under their theory, nicotine inhalers would escape FDA review as long as the manufacturer promoted them for "breathing pleasure." In an attempt to avoid that anomaly, respondents suggest that the Consumer Product Safety Commission could regulate that product. Yet respondents offer no reason why Congress would have wanted a product that manufacturers intend and consumers use as a drug-delivery device, and that poses the health risks of such a device, to be regulated by an agency with no expertise in that area.

and "advertising matter" can constitute evidence of "objective intent." *Ibid.* The regulations make clear, however, that such evidence is not the exclusive basis for determining that intent. Also relevant are: (1) all of the manufacturer's "oral or written statements," (2) "the circumstances surrounding" a product's distribution, (3) the manufacturer's "knowledge" that a product is "offered and used for a purpose for which it is neither labeled nor advertised," and (4) the manufacturer's "knowledge of facts that would give him notice" that a product "is to be used" for purposes other than those for which the manufacturer offered it. *Ibid.* As FDA has explained, the "intended use" regulations contemplate that FDA will consider "all of the relevant evidence" and decide, "from the perspective of a reasonable factfinder," whether the product is intended to affect the structure or function of the body. 61 Fed. Reg. 45,153 (1996).

Respondents' "claim" requirement also conflicts with FDA's regulatory practice. Products regulated without market claims include "caine," a street drug marketed as incense; "khat," a stimulant; cosmetics containing hormones; toothpaste containing fluoride; interferon; a food supplement containing thyroid; and novelty condoms. Gov't Br. 29-30. Respondents' effort (B&W Br. 26-27) to distinguish those regulatory measures does not accord with FDA's authoritative explanations for its actions. See 61 Fed. Reg. at 45,186-45,191; 60 Fed. Reg. 41,527-41,531 (1995).

c. There is no merit to respondents' contention (RJR Br. 15-17; B&W Br. 28-32) that FDA's longstanding interpretation will interfere with physicians' ability to prescribe approved drugs and devices for uses other than those on the labeling and inhibit the development of new uses for approved products. FDA does not prohibit physicians from prescribing approved products for off-label uses. Insofar as the manufacturer is concerned, however, FDA regulations have provided ever since 1938 that, unless FDA grants an exception, labeling should contain adequate directions for

those purposes for which a drug or device is "commonly used," even if the manufacturer has not chosen to promote those purposes in its labeling or advertising.² When a particular off-label use becomes widespread, FDA may fairly "impute the requisite intended use[] to [the] manufacturers" (J.A. 62). As FDA explained in 1972, when that occurs, "FDA will investigate it thoroughly" and "take whatever action is warranted to protect the public," including, if appropriate, "[r]equiring a change in the labeling to warn against or approve the unapproved use, seeking substantial evidence to substantiate its use [as safe and effective], restricting the channel of distribution, and even withdrawing approval of the drug and removing it from the market in extreme cases." 37 Fed. Reg. 16,504 (1972) (quoted at 61 Fed. Reg. at 45,182); see, e.g., 64 Fed. Reg. 10,994 (1999) (addressing off-label use of diet drug in "Phen Fen," which resulted in serious cardiac events); B&W Br. 31 (labeling requirement for baby aspirin used by adults to reduce heart attack risk). These steps do not interfere with the practice of medicine or the proper development of new uses for approved drugs or devices.

d. Respondents derive (RJR Br. 12; B&W Br. 11-12) their non-textual "claim" requirement from a single sentence in a 1934 Senate Report stating that "[t]he manufacturer of the article through his representations in connection with its

² Those regulations specify what constitutes "adequate directions for use" in the labeling of a drug or device under 21 U.S.C. 352(f)(1). They provide that, absent an exception, such directions must be adequate for the purposes for which the drug or device "is intended" (cross-referencing the "intended use" regulation), and then state that directions may be inadequate if they omit statements of "all conditions, purposes or uses for which the drug [or device] is intended"—"including" not only those for which it is "prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising," but also those for which it "is commonly used." 21 C.F.R. 201.5 (drugs), 801.5 (devices). That requirement, adopted in its current form in 1952 (17 Fed. Reg. 6818 (1952)) (21 C.F.R. 1.106(1)), derives from a regulation adopted in 1938. See 3 Fed. Reg. 3167 (1938).

sale can determine the use to which the article is to be put." S. Rep. No. 493, 73d Cong., 2d Sess. 3 (1934). That sentence, however, says only that representations "*can* determine" an article's intended use, not that the presence or absence of a representation is always dispositive.³

By contrast, FDA's longstanding position that "intended" effects are not limited to manufacturer claims was confirmed by the House Report on the 1976 device amendments. That report specifically rejected the proposition that a claim is dispositive and explained that the Secretary "may consider actual use of a product in determining whether or not it is a device." H.R. Rep. No. 853, 94th Cong., 2d Sess. 14 (1976). Contrary to respondents' assertion (B&W Br. 17 n.14), the 1976 House Report cannot be dismissed on the ground that it "interprets language enacted 38 years earlier," because the structure/function "device" definition was reenacted in the 1976 amendments. Gov't Br. 27.⁴

³ Respondents also take the sentence entirely out of context. It is part of a paragraph discussing when a product that is concededly subject to the Act will be regulated as either a "drug" or a "food" (or both). The sentences preceding the one respondents quote explain that "if [the product] is to be used *only* as a food it will come within the definition of food and none other," while "[i]f it contains nutritive ingredients but is sold for drug use *only*, as *clearly* shown by the labeling and advertising, it will come within the definition of drug, but not that of food"; the sentence immediately following the one respondents quote then states that a manufacturer of a laxative that is a medicated candy or chewing gum could bring its product within the definition of drug "and escape that of food" by "representing the article *fairly* and *unequivocally* as a drug product." S. Rep. No. 493, at 3 (emphasis added). The paragraph as a whole thus suggests no more than that a manufacturer, by "clearly," "unequivocally," and "fairly" representing a product as "only" one thing (*e.g.*, a drug), can negate the conclusion that it is another (*e.g.*, a food). Here, respondents have carefully avoided making claims that reflect the intended uses of their products. Nor have they made claims that their products are intended only for some *other* use that negates their status as drugs or devices, and such claims could not "fairly" be made, in light of the overwhelming evidence of intended pharmacological effects. Compare Gov't Br. 27-28.

⁴ Respondents' effort (B&W Br. 12-15) to find support for their position in the Drug Amendments of 1962 is unavailing. The 1962 amend-

e. In sum, the text, legislative history, and administrative interpretation of the Act all make clear that intended effects under the drug and device definitions are not limited to those claimed by manufacturers. And numerous judicial decisions, including many cited by respondents (RJR Br. 12, 14, B&W Br. 11-12, 21-24), confirm that intent may be determined from "any relevant source," including consumer use. Gov't Br. 28.

ments prevent a drug manufacturer from making claims about a new product, or new claims about an existing product, without first establishing that the product is effective or generally recognized as such. See *Weinberger v. Hynson, Westcott & Dunning*, 412 U.S. 609, 622 (1972). Specifically, they require manufacturers to establish that a new drug will have the effect it purports or is represented to have under the conditions "prescribed, recommended, or suggested" in its labeling. 21 U.S.C. 355(d)(5), (e)(3). In justifying that requirement, several committee reports, Members of Congress, and administration witnesses stated that drugs should be shown to be effective for their "intended" uses or purposes before they are marketed. See B&W Br. 13-15.

The quoted passages did not advert to the wholly different situation, presented here, of a product that has been marketed for many years and whose "intended" effects are shown by pervasive practices of consumers and manufacturers, without any need for claims. None of those passages purported to interpret the structure/function definition or to equate "intended" effects in that definition with uses "prescribed, recommended, or suggested" on the labeling in 21 U.S.C. 355(d). Indeed, the 1962 amendments establish that Congress did *not* equate those two concepts. Section 107(c)(4) of the amendments afforded grandfather protection for a drug "when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to that drug" prior to the amendments' effective date. 76 Stat. 789; see *USV Pharmaceutical Corp. v. Weinberger*, 412 U.S. 655 (1972). That clause plainly contemplates that there can be "intended uses" other than those identified in the labeling. See H.R. Rep. No. 2464, 87th Cong., 2d Sess. 12 (1962). After the 1962 amendments, as before, if an approved drug develops such a use—*i.e.*, if the drug becomes commonly used for an off-label purpose—FDA can respond in various ways, including by requiring that the labeling contain adequate directions for that additional use. See pp. 4-5, *supra*. If FDA imposes such a requirement, then conditions for that additional use will be "prescribed, recommended, or suggested" in the labeling, and that use will therefore have to satisfy the new drug standards of safety and effectiveness. See 21 U.S.C. 321(p)(1), 355(d)(1) and (5), 355(e)(1) and (3).

2. Respondents err in contending (UST Br. 9) that the structure/function definitions are limited to products with a medical purpose. The term "medical purpose" does not appear in the Act's definitions, and there is no term in the definitions that could serve as the basis for such a limitation.

Moreover, the drug and device definitions include as separate categories (1) products "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," and (2) products "intended to affect the structure or any function of the body." 21 U.S.C. 321(g)(1) and (h). Since the dictionary defines "medical" as "of, relating to, or concerned with physicians or with the practice of medicine," *Webster's Third* at 1402, and "medicine" as "a substance or preparation used in treating a disease," *ibid.*, respondents' medical-purpose gloss on the latter definition would eliminate any meaningful distinction between the two. Congress, however, added the latter definition because certain dangerous and ineffective products that were intended to affect the structure or function of the body, such as weight-loss products, did not fit within the treatment-of-disease category. Gov't Br. 20. If the structure/function definition required proof of a medical purpose, it would resurrect the former regime and reopen the loophole that Congress sought to close.

Respondents' medical-purpose test also conflicts with FDA's practice of regulating products that do not have a medical purpose—tanning booths, wrinkle creams, hair-growing products, stimulants (such as NoDoz), aphrodisiacs, and athletic performance enhancers. 61 Fed. Reg. at 44,677-44,678. Respondents seek to reconcile their medical-purpose test with that FDA practice by equating a medical purpose with a purpose to produce a beneficial effect on the body (UST Br. 28-30). But if that is the relevant inquiry, tobacco products qualify. "Tobacco industry scientists have themselves argued that tobacco products provide 'needed physiological benefits (increased mental alertness; anxiety reduc-

tion, coping with stress)," and that "nicotine is a very remarkable beneficent drug." 61 Fed. Reg. at 44,680.⁵

3. Respondents contend (RJR Br. 21) that, because Congress has exempted tobacco products from other health and safety statutes, those products should be excluded from the FDCA as well. Respondents have it backwards. The specific exemptions in other statutes demonstrate that Congress knows how to exempt tobacco products when it wants to. Since Congress did not exempt tobacco products from the "drug" and "device" definitions in the FDCA (even though it did exempt tobacco from the definition of "dietary supplement," 21 U.S.C. 321(ff)(1)), those products are covered by the FDCA—if, as FDA has found, they are "intended to affect the structure or any function of the body."⁶

⁵ Respondents contend (UST Br. 15; RJR Br. 18) that without a "medical claims" limitation, products such as guns, thermal clothing, air conditioners, exercise equipment, scuba-diving gear, mattresses, and even roller coasters and horror movies could be considered "devices" under the Act. FDA has never interpreted the FDCA to reach any of those products, cf. *Church of the Holy Trinity v. United States*, 143 U.S. 457, 459 (1892), and it plainly would have discretion not to take enforcement action even if they were thought by some to be covered. *Heckler v. Chaney*, 470 U.S. 821 (1985). If FDA nonetheless attempted to regulate such products, the question would arise whether it would be reasonable to press the words of the structure/function definition to the point of treating as "devices" products that do not deliver drugs to the body, that do not have intended effects similar to any other product regulated by FDA, and that implicate more directly the consumer-safety purposes of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2051 *et seq.*, than the health concerns of the FDCA (see RJR Br. 19; B&W Br. 20-21 n.17). This case does not remotely raise that question. Tobacco manufacturers have themselves characterized nicotine as a powerful drug and cigarettes as devices for delivering nicotine to the body; the intended effects of tobacco products are the same as many other products regulated by FDA (Gov't Br. 23-24), and tobacco products directly implicate the health concerns of the FDCA.

⁶ Respondents assert (RJR Br. 19-20) that the exemption in the CPSA for tobacco products is superfluous if they are drugs or devices under the FDCA, because there is a separate exemption in the CPSA for FDCA drugs and devices. When Congress enacted the CPSA in 1972, however, FDA had not yet found sufficient evidence that tobacco products are in-

4. Contrary to respondents' assertion (B&W Br. 9-10; PM Br. 7), FDA's predecessor agency did not announce in 1914 that it could not regulate tobacco products unless they were marketed with medical claims. The agency stated that "tobacco and its preparations, when labeled in such a manner as to indicate their use for the cure, mitigation, or prevention of disease, are drugs within the meaning of the act," and that "tobacco and its preparations which are not so labeled *and are used for smoking or chewing or as snuff and not for medicinal purposes* are not subject to the provisions of the act." See Gov't Br. 41 n.10. That statement, concerning the treatment-of-diseases definition now in 21 U.S.C. 321(g)(1)(B), indicates that, while health claims are *sufficient* to subject tobacco products to coverage, they are not *necessary*. Indeed, the italicized portion—which would be superfluous under respondents' reading of the Act—reinforces FDA's position that consumer use of a product can support a finding of "intended" effects even in the absence of claims.

Respondents also rely (RJR Br. 13 n.12; B&W Br. 19-20) on statements by FDA officials during the 1960s and 1970s that tobacco products were not covered by the FDCA. Those statements were made in the context of growing

tended to affect the structure or function of the body. An express exemption was therefore necessary to exclude tobacco products from the CPSA.

Respondents also argue (RJR Br. 20) that, because the Controlled Substances Act (CSA), 21 U.S.C. 801 *et seq.*, includes FDCA "drugs" and excludes "tobacco," 21 U.S.C. 802(6), (12), if the nicotine in tobacco products is a "drug," then it would simultaneously be included and excluded from the definition of "controlled substance." There is no such contradiction. Under familiar principles of statutory construction, the CSA's specific exclusion of "tobacco" prevails over its general inclusion of "drugs." Nor does the CSA's definition of "controlled substance" to mean both "drugs" and "any other substance" included in one of the CSA schedules (see 21 U.S.C. 802(6)) contradict our contention that products taken into the body for pharmacological effects have the classic characteristics of products subject to FDA regulation. The reference to "any other substance" simply permits certain substances to be controlled even without a showing that they are intended to be used as drugs.

awareness, sparked by the Surgeon General's 1964 Report, that tobacco products cause cancer and other serious health conditions. The statements reflected FDA's view that it did not have jurisdiction to regulate tobacco products based on those adverse health effects alone: because consumers used tobacco products in spite of, not because of, their cancer-causing and other harmful properties, *those* effects on the structure or function of the body were not "intended" within the meaning of the FDCA. Cf. *Personnel Administrator v. Feeney*, 442 U.S. 256, 279 (1979). The statements also reflected FDA's belief that, absent manufacturer claims, there was then insufficient evidence to warrant the conclusion that tobacco products were "intended" to affect the structure or function of the body in some *other* way.

FDA did not have such evidence until recently. In 1980, when FDA denied the petition filed by Action on Smoking and Health (ASH) due to the absence of evidence of intended effects (J.A. 50-68), no major health organization had yet determined that nicotine was addictive. By 1994, every leading health organization had concluded that it was. In 1980, evidence did not show that most consumers use tobacco products to sustain addiction and for stimulation and sedation. Evidence developed since 1980 shows that the overwhelming percentage of consumers do so. Most dramatic, recently released internal industry documents show that tobacco manufacturers have long known that consumers use their products for their pharmacological effects and have deliberately engineered them to deliver active doses of nicotine. In 1980, that evidence was not available. Gov't Br. 38-39.⁷

⁷ Respondents err in asserting (PM Br. 25) that FDA's 1980 decision was based on a supposed recognition "that its lack of jurisdiction was inherent in the FDCA and not due to lack of evidence." FDA twice stated that consumer-use of a product as a device could be a basis for finding "intended" effects or use, but that ASH had failed to produce sufficient consumer use evidence. J.A. 56-57, 61-62; see also *id.* at 54, 58. The decision also stated that FDA's statement to Congress in 1965 concerning its lack of jurisdiction was likewise based on an absence of evidence of the

While respondents now launch an "everyone has always known" attack on FDA's decision, respondents' chief executives represented to Congress in 1994, under oath, that the nicotine in tobacco products is not addictive, *Regulation of Tobacco Products: Hearing Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 103d Cong., 2d Sess. Pt. 1, at 628 (1994), and that respondents do not engineer their products to deliver active doses of nicotine, *id.* at 542, 544, 558, 598. Respondents continued to make those same assertions in this rulemaking proceeding.⁸ And, for more than 30 years, respondents withheld from the public critical information about the intended effects of the nicotine in their products. Gov't Br. 5-7.

B. Structure Of The Act

1. Respondents erroneously contend (RJR Br. 24-25) that FDA cannot regulate tobacco products as drugs or devices because the FDCA provides that drugs and devices must be proven safe, and FDA has not found that tobacco products are safe. At the outset, we note the following: First, FDA has chosen to regulate tobacco products as devices, a choice within its authority when, as here, a product is a combination of a drug and a device. 61 Fed. Reg. at 44,400-44,403.⁹ Second, the relevant standard for permitting the sale of a device is that the regulatory controls to be applied must provide a "reasonable assurance of * * * safety"

requisite intended use. J.A. 57. Respondents similarly quote (PM Br. 23) an ambiguous statement from FDA's 1977 decision (J.A. 44-49) without noting that the D.C. Circuit authoritatively interpreted the 1977 decision as likewise resting on lack of evidence. *ASH v. Harris*, 655 F.2d 236, 239 (1980); accord Gov't Br. 38 (quoting FDA brief in D.C. Circuit).

⁸ *E.g.*, 61 Fed. Reg. at 44,617, 44,670-44,671, 44,706-44,707, 44,776-44,777, 44,783, 44,789, 44,800, 44,958-44,959, 44,965-44,983, 44,986-44,987, 45,065, 45,067, 45,115, 45,141.

⁹ Because FDA has chosen to regulate tobacco products as devices rather than drugs, there is no merit to respondents' contention (RJR Br. 27-28) that, under FDA's theory, tobacco products are "new drugs" that FDA may not permit to be marketed unless approved as safe and effective.

for the device. 21 U.S.C. 360c(a). Third, that determination is made at the end of the classification process, after an expert panel studies the product and makes a recommendation, after FDA issues a proposed rule concerning the appropriate regulatory class and controls for the product, and after the public has an opportunity to comment. 21 U.S.C. 360c(b), (c) and (d). That process is often time-consuming, compare *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 n.3, 479-480 (1996), and as respondents concede (RJR Br. 29), the Act does not impose a deadline. Fourth, consistent with its usual practice, FDA decided to apply general controls to tobacco products first, rather than delaying regulation until completion of the lengthy classification process. 61 Fed. Reg. at 44,412.

Respondents contend, however, that, regardless of what additional controls may be imposed in the classification process, FDA will not be able to find that a reasonable assurance of safety exists, and that tobacco products therefore will have to be banned. That result is so unthinkable, respondents argue, that, despite the overwhelming evidence that tobacco products are devices for delivering nicotine to the body, they cannot be drug-delivery devices within the meaning of the FDCA. FDA has reasonably determined, however, that the FDCA does not require a ban on the sale of tobacco products to adults.

In classifying a device, the Act requires FDA to weigh "any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. 360c(a)(2)(C). Under that standard, devices that are dangerous in the ordinary sense of that word may be permitted to be sold if FDA finds (as it has, *e.g.*, for certain cancer-treatment products) that the health benefits to those who use them outweigh the risks. Gov't Br. 32. FDA has made such a judgment here. Although FDA decided to prohibit the sale of tobacco products to children, it found that, because so many adults are addicted to the products, it would be more dangerous to the health of those adults and to

the public health overall to remove tobacco products from the market completely than to leave them on the market for adults, subject to the Act's general controls and whatever additional controls may be imposed as a result of the classification process. In particular, FDA found that leaving tobacco products on the market provides health benefits because many addicted adults would suffer from nicotine withdrawal and there would not be adequate pharmaceuticals available for treatment, and because the black-market products that would predictably replace existing tobacco products would be even more dangerous for those users. 61 Fed. Reg. at 44,413. Respondents' assertion (RJR Br. 26) that FDA's judgment rests on factors outside FDA's mission, such as adverse effects on law enforcement, the economy, and society at-large, ignores FDA's rationale.

Even if the Act were to require tobacco products to be banned, however, that would not invalidate FDA's threshold determination that tobacco products are "devices" for delivering the "drug" nicotine. It would mean that Congress might then have to consider whether to amend the Act to permit the continued sale of those drug-delivery devices, just as it permitted the continued sale of products containing saccharin after FDA concluded that the Act required them to be banned. Gov't Br. 36-37. Respondents assert (RJR Br. 32) that a ban of tobacco products "was not reasonably in the contemplation of the enacting Congress." But if, as we have shown, compelling new evidence establishes that the nicotine in tobacco products is intended to sustain addiction and for sedation, stimulation, and weight control—and if, as respondents assert, tobacco products cannot be marketed with a reasonable assurance of safety—the Act would require a ban. The fact that the legislators who voted for the 1938 Act did not anticipate that such evidence would come to light and that tobacco products would be covered by the Act as a result—or that some might have regarded a ban as undesirable even in those circumstances—is simply not relevant to

the statutory inquiry. Congress deliberately crafted broad definitions of "drug" and "device" in 1938, and "it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed." *Oncale v. Sundowner Offshore Servs., Inc.*, 523 U.S. 75, 79 (1998).

2. In addition to disagreeing with FDA's judgment concerning whether tobacco products must be banned, respondents argue that FDA has misinterpreted several other provisions of the FDCA. Those criticisms are misguided.

a. Noting that a device is "misbranded" if "it is dangerous to health when used in the * * * manner * * * suggested in the labeling," 21 U.S.C. 352(j), respondents object (RJR Br. 27) that FDA did not explain why that provision is inapplicable to tobacco products. The reason is that, just as the benefits of some cancer treatments outweigh their health risks, the benefits of allowing tobacco products to remain on the market, subject to regulatory controls, outweigh the health risks of removing them from the market. They are therefore not "dangerous to health" within the meaning of that provision. Even if that provision were applicable, however, FDA would have discretion to decide that, given the danger to the health of addicted adults of removing tobacco products from the market, it should not be enforced against those products. *Chaney*, 470 U.S. at 835.¹⁰

¹⁰ For the same reason, there is no merit to respondents' argument (RJR Br. 30) that FDA has failed to comply with a section of the Act providing that, "[i]f [FDA] finds that there is a reasonable probability that a device * * * would cause serious, adverse health consequences or death, [FDA] shall issue an order requiring the [manufacturer] * * * to immediately cease distribution of such device." 21 U.S.C. 360h(e)(1)(A). FDA's finding that banning tobacco products would create greater dangers than leaving them on the market subject to regulatory controls makes that provision inapplicable. But even if it were applicable, FDA would have discretion not to issue a cease-distribution order. *Chaney*, 470 U.S. at 835. Although the provision uses the word "shall," FDA has interpreted it as permissive rather than mandatory. See 21 C.F.R. 810.10(a) (FDA "may issue a cease distribution and notification order"). FDA's interpretation is

b. Respondents contend (RJR Br. 28) that, because a device is misbranded if it fails to bear "adequate directions for use," and FDA has not required such directions for tobacco products, "it must be FDA's view that adequate directions for use of tobacco products cannot be written." FDA may grant an exemption from the adequate directions requirement, however, when it determines they are "not necessary for the protection of the public health." 21 U.S.C. 352(f). One such circumstance is when "adequate directions for common uses [of the device] are known to the ordinary individual." 21 C.F.R. 801.116. Because it is "common knowledge" how tobacco products are used, FDA reasonably decided an exemption was warranted. 61 Fed. Reg. at 44,465.

c. Finally, respondents argue (RJR Br. 28-29) that FDA failed to apply a misbranding provision that requires "adequate warnings against use * * * by children." 21 U.S.C. 352(f)(2). FDA concluded, however, that the familiar "Surgeon General's warnings" required by other federal statutes satisfy Section 352(f)(2). 61 Fed. Reg. at 44,465. That rationale is not "disingenuous," as respondents suggest. It reflects FDA's reasonable judgment that no warnings are likely to be effective for children, *id.* at 44,468, 44,511, and that the Surgeon General's warnings serve the purposes of Section 352(f)(2) as well as any that FDA could devise.

C. Tobacco-Specific Statutes

Respondents concede (RJR Br. 36) that "the tobacco-specific statutes do not repeal any part of the FDCA or 'pre-empt' any action by FDA." They nevertheless submit (*ibid.*) that those very same statutes should preclude FDA from regulating tobacco products. Respondents are wrong.

reasonable, because "shall" sometimes means "'should,' 'will,' or even 'may,'" *Gutierrez de Martinez v. Lamagno*, 515 U.S. 417, 432 n.9 (1995); because enforcement authority is usually discretionary; and because a cease-distribution order is only an interim step in a process that leads to a "recall order," which is itself discretionary, 21 U.S.C. 360h(e)(2)(A).

1. a. Respondents contend (PM Br. 37-41) that FCLAA precludes FDA regulation because FCLAA forecloses a ban on tobacco products, while FDA's determination that tobacco products are drug-delivery devices would necessarily lead to a ban. For three reasons, that contention is without merit. First, as we have shown, FDA's determination that tobacco products are covered by the Act as drug-delivery devices does not mean that they must be banned.

Second, FCLAA does not foreclose a ban on tobacco products. By its terms, FCLAA only prevents FDA from requiring any "statement relating to smoking and health, other than the statement required by" FCLAA itself. 15 U.S.C. 1334(a). Respondents' contention (PM Br. 38) that the "policy" statement in 15 U.S.C. 1331 precludes a ban finds no support in that provision's text, and it ignores the holding in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), that FCLAA "merely prohibit[s] state and federal rulemaking bodies from mandating particular cautionary statements on cigarette labels," *id.* at 518, and that Section 1331 states not a broad policy of protecting the continued marketing of cigarettes, but a far more limited policy of "protecting the national economy from the burden imposed by diverse, nonuniform, and confusing cigarette labeling and advertising regulations," *id.* at 514. See also *id.* at 534 (Blackmun J., concurring and dissenting); *Medtronic*, 518 U.S. at 488 (FCLAA preempts only a "limited set" of requirements).

Third, even if FDA's coverage determination were to result in a ban on the sale of tobacco products under the FDCA and Section 1331 were to preclude one, that still would not undermine FDA's coverage determination. It would simply mean that FCLAA (as the more specific statute) would preclude a ban, and FDA would therefore be required to adopt measures short of a complete ban to regulate tobacco products. Nothing in FCLAA, for example, would preclude FDA from continuing with its current regulatory program of pre-

venting sales of tobacco products to minors or from requiring safer ingredients or a safer filter.

b. Respondents further argue (PM Br. 41-42) that FDA's coverage determination is precluded by FCLAA because the FDCA requires FDA to impose labeling requirements, such as adequate directions for use and warnings for children, while FCLAA prevents FDA from imposing those requirements. As we have explained, however, FDA exempted tobacco products from the FDCA's adequate directions requirement, and it reasonably determined that the Surgeon General's warnings are sufficient warnings for children. See p. 16, *supra*.¹¹ In any event, to the extent that FCLAA precludes FDA from imposing particular restrictions on tobacco products that the FDCA otherwise would require, the more specific statute would govern and FDA would be limited to regulating tobacco products in other ways.¹²

2. Respondents contend (NACS Br. 14, 18-19) that FDA's coverage determination is precluded by ADAMHA because ADAMHA generally permits States to decide what measures to adopt to curb youth tobacco use, while FDA's tobacco regulations preempt state laws that are "different from, or in addition to," FDA's requirements. 21 U.S.C. 360k(a)(1). ADAMHA, however, simply conditions certain federal funding on the States' enactment of their own laws against tobacco use. Gov't Br. 47. It does not address whether FDA

¹¹ Respondents erroneously contend (PM Br. 42) that FCLAA precludes FDA from requiring tobacco-product labeling to bear the statement "Nicotine-Delivery Device for Persons 18 or Older." Because that statement simply informs consumers about the products' intended and lawful use, and does not contain any warning about the health dangers of tobacco use, it is not a statement "relat[ing] to smoking and health" within the meaning of 15 U.S.C. 1334(a). Even if it were, however, that would lead only to invalidation of that requirement. It would not affect the conclusion that tobacco products are drug-delivery devices under the FDCA.

¹² There likewise is no inconsistency between FDA's actions and the Comprehensive Smokeless Tobacco Health Education Act of 1986, 15 U.S.C. 4401 *et seq.*, since as respondents concede (UST Br. 31), it was modeled on FCLAA and contains the same basic requirements. Gov't Br. 46.

may conclude that tobacco products are drug-delivery devices and subject to federal regulation as well. Moreover, contrary to respondents' assertion (RJR Br. 46-47), FDA's regulations do not divest States of authority to regulate tobacco products. States are free to impose whatever requirements they choose when there is no parallel FDA requirement; and where there are federal requirements, the States may impose substantially similar ones. *Medtronic*, 518 U.S. at 496-497; 21 C.F.R. 808.1(d)(2). In addition, the FDCA authorizes FDA to exempt from preemption state laws that impose more stringent requirements than FDA's, 21 U.S.C. 360k(b), and FDA has done so on many occasions. And while respondents object to that regime as insufficiently sensitive to state interests (NACS Br. 18-19), an amici brief joined by 40 States concludes (Br. 19) that "FDA's authority to regulate tobacco products is authorized by law, and is a critically important part of the effort to limit the use of tobacco products by minors."

D. *Chevron* Deference

Respondents err in contending (RJR Br. 47-50) that this case should be resolved entirely outside the *Chevron* framework. As respondents note (RJR Br. 48), this case involves the construction of both the FDCA, which FDA enforces, and tobacco-specific statutes, which it does not. But that does not mean that the *Chevron* framework should be discarded. Instead, the Court should first decide under *Chevron* whether FDA's interpretation of the Act it administers is permissible. If the Court concludes that it is, the Court should then decide independently whether FDA's authority under the FDCA has been divested by the tobacco-specific statutes. *NASA v. FLRA*, 119 S. Ct. 1979, 1984-1985 (1999). As we have shown, FDA's interpretation is based on a permissible reading of the FDCA, and the tobacco-specific statutes do not withdraw FDA's authority.

Respondents similarly err in contending (RJR Br. 49) that the *Chevron* framework does not apply because FDA has

changed its position on whether tobacco products are covered by the Act. Under *Chevron*, a change in agency position is entitled to full deference, as long as the agency offers a reasoned analysis for the change. See 467 U.S. at 863-864; *Rust v. Sullivan*, 500 U.S. 173, 186-187 (1991); *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). FDA supplied such an analysis here. FDA adhered to its longstanding legal position that a finding of "intended" effects may be based on evidence other than manufacturer claims, and it found compelling new evidence that tobacco products are intended to be used to sustain addiction and for stimulation and sedation.

Finally, respondents argue (RJR Br. 47-48) that this case should be resolved against FDA at the first step of *Chevron*. The relevant indicia of congressional intent, however, do not come close to establishing that Congress "directly addressed the precise question at issue" and "unambiguously expressed [its] intent" that tobacco products fall outside the reach of the FDCA. 467 U.S. at 843. To the contrary, the text, legislative history, and administrative interpretation of the Act strongly support FDA's conclusion that, given the overwhelming evidence that the nicotine in tobacco products is intended to be used to sustain addiction and as a sedative, stimulant, and appetite suppressant, tobacco products are drug-delivery devices within the meaning of the FDCA. At the very least, FDA's conclusion is based on "a permissible construction" of the Act. *Ibid.*

* * * * *

For the foregoing reasons and those in our opening brief, the judgment of the court of appeals should be reversed.

SETH P. WAXMAN
Solicitor General

OCTOBER 1999

APPENDIX

Section 801.4 of 21 C.F.R. states as follows:

§ 801.4 Meaning of "intended uses."

The words *intended uses* or words of similar import in §§801.5, 801.119, and 801.122 refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the devices, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.

(1a)

Section 801.5 of 21 C.F.R. states as follows:

§ 801.5 Medical devices; adequate directions for use.

Adequate directions for use means directions under which the layman can use a device safely and for the purposes for which it is intended. Section 801.4 defines *intended use*. Directions for use may be inadequate because, among other reasons, of omission, in whole or in part, or incorrect specification of:

(a) Statements of all conditions, purposes, or uses for which such device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the device is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the device can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.

(b) Quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions.

(c) Frequency of administration or application.

(d) Duration of administration or application.

(e) Time of administration or application, in relation to time of meals, time of onset of symptoms, or other time factors.

(f) Route or method of administration or application.

(g) Preparation for use, i.e., adjustment of temperature, or other manipulation or process.

(8)
No. 98-1152

Supreme Court, U.S.

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OFFICE OF THE CLERK

IN THE
Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, *et al.*,

Petitioners,

v.

BROWN AND WILLIAMSON TOBACCO CORP., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

**BRIEF OF *AMICUS CURIAE* AMERICAN
CANCER SOCIETY, INC. IN SUPPORT
OF PETITIONERS**

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PRELIMINARY STATEMENT

This brief is submitted by the American Cancer Society ("ACS") as *amicus curiae*¹ urging reversal of a decision by the United States Court of Appeals for the Fourth Circuit that invalidated the regulation of tobacco products by the Food and Drug Administration ("FDA")² under the Food, Drug, and Cosmetic Act ("FDCA").³

INTEREST OF ACS

ACS is a non-profit public health organization with a membership of over 2.3 million volunteers throughout the country, including over 50,000 physicians. ACS is committed to one goal — the control and elimination of cancer through advocacy, education, research and service.

Research conducted and supported by ACS since the 1950s has played a pivotal role in identifying the use of tobacco products as a major cause of cancer. It is now undisputed that tobacco use greatly increases one's risk of developing cancer of the lungs, mouth, throat, larynx, bladder and other organs.⁴ Indeed, about 87% of lung cancer deaths and 30% of all cancer

1. All parties have consented to the filing of this brief by letters filed with the Clerk. Counsel for ACS authored this brief in whole, and no person or entity, other than ACS, made a monetary contribution to its preparation or submission.

2. 61 Fed. Reg. 44,396 (1996).

3. 21 U.S.C. § 301, *et seq.*

4. American Cancer Society, *Prevention and Risk Factors*, at 1 (June 1999).

deaths are attributable to the use of tobacco products.⁵ In total, more than 400,000 people die prematurely each year from diseases attributable to tobacco use.⁶

ACS has been in the forefront of educating the public about the risks of tobacco use, focusing particularly on the nation's youth. ACS has repeatedly urged the FDA to assert jurisdiction over tobacco products and strongly endorsed the FDA's rule-making proceedings in this case. Because of the importance of tobacco control to ACS' mission, ACS sought and obtained permission to file this *amicus* brief to place before the Court the views of members of the public and health professionals committed to the eradication of cancer.

SUMMARY OF ARGUMENT

The number one health problem in the nation today is tobacco use. Adolescents have again begun smoking in greater numbers than since the 1960s — in part in response to alluring advertising and promotion by the tobacco industry. A dramatic increase in promotion in the last decade includes the use of brand name products that appeal to adolescents, sponsorship of sporting events, and payments to celebrities and film stars to glamorize smoking. These sophisticated marketing techniques far outstrip existing regulatory checks on the industry.

Statistical data readily demonstrate the magnitude of the problem. Over a recent eight-year period, tobacco use by youths

5. American Cancer Society, *Cancer Risk Report* — 1998.

6. Centers for Disease Control, *Cigarette Smoking — Attributable Mortality and Years of Potential Life Lost — United States, 1990*, MORBIDITY AND MORTALITY WEEKLY REPORT, Aug. 27, 1993, at 645-49.

increased by 30%.⁷ More than 3 million American children and teenagers now smoke cigarettes, and every 30 seconds a child in the United States becomes a regular smoker.⁸ In addition, some 1 million male high school students use smokeless tobacco⁹ — a practice which has become particularly popular as a result of advertising focusing on flavored brands and youth-oriented themes.¹⁰ In percentage terms, nearly half of male high school students and more than a third of female students use some form of tobacco.¹¹

Moreover, adolescents have begun to use tobacco at very early ages and find it difficult to stop. The average teen smoker starts at 13 and becomes a regular smoker by age 14.5.¹² Although some 70% of adolescents regret their decision to

7. Centers for Disease Control, *Incidence of Initiation of Cigarette Smoking — United States, 1965-1996*, MORBIDITY AND MORTALITY WEEKLY REPORT, Oct. 9, 1998, at 837-40.

8. Centers for Disease Control, *Preventing Tobacco Use Among Young People: A Report of the Surgeon General*, at 58 (1994).

9. 61 Fed. Reg. at 44,398.

10. Centers for Disease Control, *Smokeless Tobacco Brand Preference and Brand Switching Among U.S. Adolescents and Young Adults* (1995).

11. Centers for Disease Control, *Tobacco Use Among High School Students — United States, 1997*, MORBIDITY AND MORTALITY WEEKLY REPORT, Apr. 3, 1998, at 229-33.

12. Robert Wood Johnson Foundation Survey, *Results of a National Household Survey to Assess Public Attitudes About Policy Alternatives for Limiting Minors' Access to Tobacco Products* (Dec. 1994).

use tobacco,¹³ less than one in seven has successfully quit.¹⁴ ACS and other health organizations thus recognize that tobacco use by youth is a pediatric disease.

The reason why youths cannot readily stop the use of tobacco lies in the addictive properties of the drug nicotine — a fact which has become public knowledge only in recent years as a result of painstaking scientific research demonstrating that nicotine is similar to amphetamines, cocaine and morphine in causing compulsive drug-seeking behavior.¹⁵ Indeed, there is a higher percentage of addiction among tobacco users than among users of cocaine or heroin.¹⁶ Bolstering the scientific consensus on nicotine are recently unmasked tobacco industry deliberations, demonstrating the industry's long-standing knowledge of nicotine's effects.¹⁷

Responding to the alarming increase in tobacco use among youth and the scientific consensus on the addictive effects of nicotine, the FDA acted in 1996 to regulate tobacco products as "drugs" and "devices" under the FDCA, seeking as a first step to restrict the advertising and sale of tobacco products to

13. The George H. Gallup Int'l Institute, *Teenage Attitudes and Behavior Concerning Tobacco*, at 54 (Sept. 1992).

14. Centers for Disease Control, *Selected Cigarette Smoking Initiation and Quitting Behaviors Among High School Students — United States, 1997*, MORBIDITY AND MORTALITY WEEKLY REPORT, May 22, 1998, at 386-89.

15. 61 Fed. Reg. at 44,700.

16. *Id.* at 44,812-13.

17. *Id.* at 44,856, *et seq.*

minors.¹⁸ The FDA's initiative was firmly grounded in the law and holds out the promise of protecting the health of the coming generation of Americans.

ARGUMENT

I.

CONGRESS VESTED BROAD REMEDIAL AUTHORITY IN THE FDA.

The Food and Drug Act of 1906 vested the FDA with limited jurisdiction over "drugs" as narrowly defined in medical practice.¹⁹ In 1938 Congress enacted the FDCA to expand the FDA's jurisdiction to include "devices" that are "intended to affect the structure or any function of the body."²⁰ Congress said that this legislation was "essential if the consumer is to be protected against a multiplicity of abuses not subject to" preexisting law.²¹ In explaining the principles of construction applicable to the FDCA, this Court stated in 1943:

By the Act of 1938, Congress extended the range of . . . control over illicit and noxious articles The purposes of this legislation . . . touch phases of the lives and health of people which . . . are largely beyond self-protection. Regard for these

18. *Id.* at 44,616, *et seq.*

19. See *United States v. Bacto-Unidisk*, 394 U.S. 784, 793-94 (1969).

20. *Id.* at 794-98.

21. S. Rep. No. 646, 74th Cong. 1st Sess., at 1 (1935).

purposes should infuse construction of the legislation if it is to be treated as a working instrument of government²²

More than two decades later, this Court echoed these words in the leading decision construing the FDCA:

remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health²³

In so ruling, this Court emphasized that in extending the reach of the original statute, "Congress fully intended that the Act's coverage be as broad as its literal language indicates — and . . . broader than any strict medical definition might otherwise allow."²⁴

Although the FDCA as enacted in 1938 covered "devices," the statute did not provide for comprehensive regulatory control.²⁵ In 1976 Congress filled this gap by passing the Medical Device Amendments of 1976, which vested authority in the FDA to impose restrictions on the sale of devices based on the risk posed to the public.²⁶ Despite this amendment, the statute proved inadequate because of technical requirements

22. *United States v. Dotterweich*, 320 U.S. 277, 280 (1943).

23. *Bacto-Unidisk*, 394 U.S. at 798.

24. *Id.*

25. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475-77 (1996).

26. *Id.*; see 21 U.S.C. § 360c(a)(1).

for classifying a product as either a "drug" or a "device."²⁷ In 1990 Congress responded by enacting the Safe Medical Devices Act of 1990, which added new powers for FDA regulation of "combination"²⁸ products consisting of components of both drugs²⁹ and devices.³⁰

From the statutory history of the FDCA and this Court's decisions construing the statute, three fundamental principles emerge. First, the progressive expansion of the FDA's powers makes plain that "the Act's coverage be as broad as its literal language indicates"³¹ — that the FDCA "be given a liberal construction consistent with the Act's overriding purpose to protect the public health."³² Thus, for example, in determining

27. See S. Rep. 101-513, 101st Cong., 2d Sess., at 30 (1990).

28. 21 U.S.C. § 353(g)(1).

29. 21 U.S.C. § 321(g)(1)(C) defines "drug" to include "articles (other than food) intended to affect the structure or any function of the body of man"

30. 21 U.S.C. § 321(h)(3) defines "device" to include:

an instrument, apparatus, implement, machine, contrivance . . . or other similar or related article, including any component, part, or accessory, which is . . . intended to affect the structure or any function of the body of man . . . and which does not achieve its primary intended purposes through chemical action within or on the body of man . . . and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

31. *Bacto-Unidisk*, 394 U.S. at 798.

32. *Id.*

whether a drug or device is "intended to affect the structure or any function of the body" within the meaning of the FDCA,³³ it is imperative to "pierce all of a manufacturer's subjective claims of intent and even his misleading[] . . . labels"³⁴ by determining objective intent³⁵ and the actual use of products by consumers.³⁶ Were the FDA "bound by the manufacturer's subjective claims of intent,"³⁷ artful promotion of a toxic drug would shackle the FDA in achieving the statute's remedial purposes.

Second, as this Court has recognized, the FDA is particularly well-equipped to administer the FDCA by reason of the agency's "specialization, . . . insight gained through experience and . . . flexible procedure."³⁸ This Court has directed that "substantial weight [be given] to the agency's view of the statute."³⁹ In short,

33. See notes 29 & 30, *supra*.

34. *National Nutritional Foods Ass'n v. FDA*, 504 F.2d 761, 789 (2d Cir. 1974), *cert. denied*, 420 U.S. 946 (1975).

35. *Id.* See also 21 C.F.R. §§ 201.128, 801.4 (FDA regulations define "intended use" in terms of the "objective intent of the persons legally responsible for . . . labeling . . .").

36. See H.R. Rep. No. 853, 94th Cong., 2d Sess., at 14 (1976) (legislative history of Medical Device Amendments of 1976); S. Rep. No. 361, 74th Cong., 1st Sess., at 4 (1935) (legislative history of FDCA).

37. *National Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325, 334 (2d Cir. 1977).

38. *Weinberger v. Bentex Pharm.*, 412 U.S. 645, 654 (1973) (quoting *Far Eastern Conference v. United States*, 342 U.S. 570, 574-75 (1952)).

39. *Medtronic, Inc.*, 518 U.S. at 496.

It is enough for us that the expert agency charged with the enforcement of remedial legislation has determined that . . . regulation is desirable for the public health, for we are hardly qualified to second-guess the Secretary's medical judgment.⁴⁰

Finally, in applying its "insight gained through experience", the FDA must necessarily respond to advances in scientific learning and new realities. As this Court has repeatedly noted, "[regulatory] agencies do not establish rules of conduct to last forever" and "must be given ample latitude to 'adapt their rules and policies to the demands of changing circumstances.'"⁴¹ Without the power to adapt to change, regulation would be "stereotyped" and the public interest disserved.⁴²

40. *Bacto-Unidisk*, 394 U.S. at 791-92. See also *Chevron U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837, 843 (1984) ("The power of an administrative agency . . . necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress." (quoting *Morton v. Ruiz*, 415 U.S. 199, 231 (1974))).

41. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983) (quoting *American Trucking Ass'ns, Inc. v. Atchison, Topeka and Santa Fe Ry. Co.*, 387 U.S. 397, 416 (1967), & *Permian Basin Area Rate Cases*, 390 U.S. 747, 784 (1968)). See also *Rust v. Sullivan*, 500 U.S. 173, 186 (1991) ("[a]n agency is not required to 'establish rules of conduct to last forever . . .'").

42. See *NBC v. United States*, 319 U.S. 190, 219-20 (1943).

II.

**THE FDA PROPERLY ASSERTED JURISDICTION
OVER TOBACCO PRODUCTS TO PROTECT
AMERICA'S YOUTH FROM AN ADDICTIVE DRUG.**

**A. Lacking Knowledge Of The Addictive Properties Of
Nicotine, The Government Initially Relied On
Disclosure Of Health Risks To Stem Tobacco Use.**

This Court has noted that "physicians ha[ve] suspected a link between smoking and illness for centuries"⁴³ By the early 1960s the volume of scientific evidence prompted the U.S. Surgeon General to convene an advisory committee on the subject.⁴⁴ In 1964 the committee's landmark study concluded that "[c]igarette smoking is a health hazard of sufficient importance in the United States to warrant appropriate remedial action."⁴⁵ At that time the scientific community at large did not understand what was well known by the tobacco industry — that addiction to nicotine in tobacco is the major reason for continued smoking. Only in the 1990s has the medical community realized that nicotine is as addictive as other drugs, such as amphetamines, cocaine and morphine.

43. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 513 (1992).

44. *Id.*

45. *Id.* (quoting U.S. Dep't of Health, Education and Welfare, U.S. Surgeon General's Advisory Committee, Smoking and Health 33 (1964)).

Unaware that tobacco products are, in essence, drug delivery devices for nicotine, the FDA declined jurisdiction under the FDCA in the 1960s⁴⁶ — a position entirely consistent with judicial precedent, *FTC v. Liggett & Myers Tobacco Co.*,⁴⁷ which had held that cigarettes merely "soothe the troubled mind of modern man" and do not constitute "drugs" "intended to affect the structure or any function of the body"⁴⁸

Federal policy initially focused on the limited goal of educating the public about the potential dangers of cigarette smoking to health. Having previously regulated cigarette advertising under the Federal Trade Commission Act, the Federal Trade Commission in 1964 proposed regulations requiring a clear and prominent disclosure on all cigarette packages and advertising that "cigarette smoking is dangerous to health and may cause death from cancer and other diseases."⁴⁹ States likewise acted to regulate advertising.⁵⁰ In mid-1965, after extensive deliberations, Congress enacted the Federal Cigarette Labeling and Advertising Act mandating that cigarette packages carry the warning: "CAUTION: CIGARETTE SMOKING MAY BE HAZARDOUS TO

46. See, e.g., Hearings Before the House Comm. on Interstate and Foreign Commerce on Bills Regulating the Labeling and Advertising of Cigarettes and Relating to Health Problems Associated with Smoking, 88th Cong., 2d Sess., at 56 (1964).

47. 108 F. Supp. 573 (S.D.N.Y. 1952), *aff'd*, 203 F.2d 955 (2d Cir. 1953) (construing provision of Federal Trade Commission Act comparable to the FDCA).

48. *Id.* at 574, 577.

49. *Cipollone*, 505 U.S. at 513.

50. *Id.*

YOUR HEALTH."⁵¹ Congress imposed no restrictions on advertising at the time.⁵²

In 1969 the FTC reinstituted its 1964 proceedings to address restrictions on cigarette advertising.⁵³ Another initiative came from the Federal Communications Commission, which proposed a prohibition of cigarette advertising on broadcast media.⁵⁴ In this context, Congress enacted the Public Health Cigarette Smoking Act of 1969, which amended the 1965 legislation to require a more stringent warning that cigarette smoking is "dangerous", as well as imposing a complete prohibition of cigarette advertising on television and radio.⁵⁵

In the 1970s the FDA was petitioned by public citizens' groups to regulate cigarettes under the FDCA. Still in the dark about the addictive properties of nicotine, the FDA declined jurisdiction. On review to the Court of Appeals the petitioners challenged what they characterized as no more than "blind adherence" by the FDA to the court's decision in *FTC v. Liggett & Myers Tobacco Co.*⁵⁶ In dismissing the challenge, the Court of Appeals concluded that the FDA "would not be performing [its] statutory duty" if it were "to ignore clearly relevant judicial

51. Pub. L. 89-92, 79 Stat. 282 (1965), as amended, 15 U.S.C. §§ 1331-1340.

52. *Cipollone*, 505 U.S. at 514.

53. *Id.* at 514-15.

54. *Id.*

55. Pub. L. 91-222, 84 Stat. 87 (1970), as amended, 15 U.S.C. §§ 1331-1340.

56. See note 47, *supra*.

decisions."⁵⁷ The FDA's position clearly reflected the state of scientific knowledge at the time.

B. A Scientific Consensus On The Addictive Properties Of Nicotine As A Drug Impelled The FDA To Regulate Tobacco Products.

1. The Research

In studies conducted on animals in the early 1980s scientists first discovered that nicotine causes repeated, compulsive use of the drug — a distinguishing characteristic of addictive drugs.⁵⁸ In 1983 scientists demonstrated that nicotine was addictive in humans.⁵⁹ In the mid-1980s scientists discovered that nicotine produces withdrawal syndromes.⁶⁰ In the early 1990s studies demonstrated that "[n]icotine, like other addictive drugs (*e.g.*, cocaine, amphetamine, and morphine), produces its addictive effects by actions increasing dopamine concentrations within the mesolimbic system of the brain."⁶¹ Nicotine exposure was also shown to cause an increase in the number of nicotinic receptors in the central nervous system,

57. *Action on Smoking and Health v. Harris*, 655 F.2d 236, 242 (D.C. Cir. 1980). The decision by the Court of Appeals is also supported by this Court's subsequent holding in *Heckler v. Chaney*, 470 U.S. 821, 837-38 (1985), in which the Court held unreviewable under the Administrative Procedure Act a determination by the FDA to refrain from taking enforcement action under the FDCA.

58. 61 Fed. Reg. at 45,229.

59. *Id.* at 45,230.

60. *Id.* at 45,231.

61. *Id.*

associated with the development of nicotine tolerance.⁶² In the early 1990s, nicotine was shown to produce effects on the brain associated with changes in mood and alertness.⁶³ Finally, by the mid-1990s, it was apparent that nicotine replacement therapies were effective in assisting smokers to quit, thereby providing additional evidence that nicotine is the ingredient in tobacco products that causes addiction.⁶⁴

In short, by 1995 when the FDA commenced the rule-making proceedings at issue in this case, "[e]very expert organization that ha[d] commented on whether nicotine is addictive ha[d] concluded that it is"⁶⁵ — including the U.S. Surgeon General, the Royal Society of Canada, the World Health Organization, the American Medical Association and the U.K. Medical Research Council.⁶⁶

2. Industry Deliberations

This scientific consensus, reached only after meticulous research in the 1980s and 1990s, confirmed what the tobacco industry already knew. Deliberations only recently unmasked to public view revealed that the tobacco industry had long recognized that nicotine is a powerful drug.

As early as 1962, a consultant to British American Tobacco stated in an internal document that " 'nicotine is a very

62. *Id.* at 45,232.

63. *Id.* at 45,231.

64. *Id.* at 45,232.

65. *Id.* at 44,703.

66. *Id.* at 44,702-03.

remarkable beneficent drug that both helps the body to resist external stress and also can as a result show a pronounced tranquillising effect ' " ⁶⁷ A 1963 report commissioned by British American Tobacco likewise acknowledged that a denial of nicotine intake to chronic smokers produces a " 'crav[ing] for renewed drug intake ' " ⁶⁸

In 1972 an R.J. Reynolds executive explained that " 'the tobacco industry may be thought of as being a specialized, highly ritualized and stylized segment of the pharmaceutical industry . . . based upon design, manufacture and sale of attractive dosage forms of nicotine ' " ⁶⁹ Perhaps most graphically, a Philip Morris scientist in 1972 characterized the cigarette in these terms:

"Think of the cigarette pack as a storage container for a day's supply of nicotine

Think of the cigarette as a dispenser for a dose unit of nicotine

Think of a puff of smoke as the vehicle of nicotine

67. C. Ellis, *The Smoking and Health Problem*, at 15-16 (1962) (quoted in 61 Fed. Reg. at 44,882).

68. C. Haselbach *et al.*, *A Tentative Hypothesis on Nicotine Addiction*, at 2 (1963) (quoted in 61 Fed. Reg. at 44,884).

69. C. Teague, *Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein*, at 2 (1972) (quoted in 61 Fed. Reg. at 44,869).

Smoke is beyond question the most optimized vehicle of nicotine and the cigarette the most optimized dispenser of smoke."⁷⁰

Philip Morris scientists subsequently acknowledged that cigarettes serve as " 'a narcotic, tranquilizer, or sedative' " ⁷¹ and that " '[n]icotine is a powerful pharmacological agent with multiple sites of action . . . known to have effects on the central and peripheral nervous system' " ⁷²

It has become apparent in recent years that the tobacco companies' research on the effects of nicotine rivals that of traditional pharmaceutical companies. As the FDA found:

Before marketing a prescription drug, a pharmaceutical company studies the pharmacokinetics of the drug (how it is absorbed into the body, metabolized, and excreted), the pharmacodynamics of the drug (what specific effects the drug has on the body's chemistry and metabolism as it makes its way through the body), and the clinical effects of the drug (whether the drug is effective in producing the desired therapeutic or physiological effects). The cigarette manufacturers have conducted or funded the same studies for nicotine. As a result, the cigarette

70. W. Dunn, *Motives and Incentives in Cigarette Smoking*, at 5-6 (1972) (quoted in 61 Fed. Reg. at 44,856).

71. A. Udow, *Why People Start to Smoke* (1976) (quoted in 61 Fed. Reg. at 44,857).

72. J. Charles, *Nicotine Receptor Program* (1980) (quoted in 61 Fed. Reg. at 44,857-58).

manufacturers' understanding of the pharmacological effects and uses of nicotine are closely analogous to — if not more extensive and sophisticated than — the understanding any pharmaceutical company has of traditional drug products.⁷³

Indeed, R.J. Reynolds recently announced a new venture to compete head-to-head with pharmaceutical companies.⁷⁴ Capitalizing on its knowledge of nicotine, R.J. Reynolds hopes to develop nicotine-based drugs to treat Alzheimer's, Parkinson's and other diseases.⁷⁵

In designing and manufacturing cigarettes, the tobacco industry has developed what Philip Morris concedes to be " 'complex computer models to help determine nicotine and tar deliveries . . . allow[ing] blend ingredients, filter and paper components, and numerous other variables to be considered simultaneously. . . .' " ⁷⁶ The industry establishes parameters for nicotine at the tobacco growing stage.⁷⁷ In making purchasing decisions, the industry inspects leaf characteristics to determine nicotine content — the higher stalk tobacco leaves contain more nicotine than lower stalk leaves on the same plant.⁷⁸ The industry uses leaf blending as a primary means to

73. 61 Fed. Reg. at 44,911-12.

74. S.L. Hwang, *R.J. Reynolds Hopes to Spin Nicotine Into Drugs*, WALL STREET JOURNAL, June 28, 1999, at B1.

75. *Id.*

76. 61 Fed. Reg. at 44,980.

77. *Id.* at 44,981.

78. *Id.* at 44,982.

control nicotine levels. Leaf blending produces consistency and uniformity to negate variations in nicotine associated with genetics and soil and climatic conditions.⁷⁹ The industry likewise controls nicotine content through inputs during manufacturing, such as reconstituted tobacco and ammonia compounds.⁸⁰ During the process, quality control checks are used to determine the exact amount of nicotine in the product.⁸¹ In particular, ammonia added to reconstituted tobacco can increase the level of "free" nicotine in the cigarette, constituting in the words of a cigarette manufacturer, "the soul of Marlboro." ⁸² In sum,

cigarette manufacturers carefully control and manipulate the nicotine delivery of their commercially marketed cigarettes to provide smokers with a pharmacologically active dose of nicotine. Among other practices, the manufacturers use high-nicotine blends that increase nicotine deliveries . . . ; rely on filtration and ventilation technologies that selectively remove more tar than nicotine; add ammonia compounds that increase the delivery of "free" nicotine; and carefully control the nicotine level in all cigarettes An inevitable consequence of these practices is to keep consumers smoking by sustaining their addiction.⁸³

79. *Id.* at 44,983-84.

80. *Id.* at 44,984-86.

81. *Id.* at 44,985.

82. *Id.* at 44,986.

83. *Id.* at 44,993-94.

3. *The FDA's Conclusions*

On the basis of the scientific consensus on nicotine and the tobacco industry's own concessions, the FDA commenced rule-making proceedings to address whether tobacco products should be subject to jurisdiction under the FDCA. The evidence before the FDA compelled two fundamental findings of fact. First, nicotine, like amphetamines, cocaine and morphine, "substantially alters the structure and function of the brain and other systems of the body."⁸⁴ When cigarette smoke is inhaled, nicotine enters the mouth, passes into the lungs, is absorbed into the bloodstream and diffuses into the brain — all within approximately 11 seconds.⁸⁵ In the brain, nicotine binds to unique receptors on the surfaces of brain cells, causing "the number of nicotinic receptors . . . to increase and significantly alter[ing] the brain's normal electrical and metabolic activity"⁸⁶ Nicotine can produce both sedating and stimulating effects, depending on dose and circumstances.⁸⁷

Second, "nicotine causes and sustains addiction" by directly affecting the so-called mesolimbic system of the brain that signals pleasure and reward and modulates emotions.⁸⁸ Upon stimulation by an addictive substance, the mesolimbic system responds by rewarding repeated consumption of the

84. *Id.* at 44,698.

85. *Id.* at 44,698-99.

86. *Id.* at 44,699-700.

87. *Id.*

88. *Id.* at 44,700.

substance.⁸⁹ Nicotine, like amphetamines, cocaine and morphine, causes compulsive drug-seeking behavior associated with drug addiction.⁹⁰ Research demonstrates, for example, that from 77% to 92% of smokers are addicted and that tobacco users show a higher percentage of addiction than users of other drugs, such as cocaine and heroin.⁹¹

From these findings of fact, the FDA reached three inevitable legal conclusions. First, because "nicotine's addictive and other pharmacological effects and uses are so widely recognized . . . they must be considered foreseeable to a reasonable tobacco manufacturer."⁹² Accordingly, nicotine is "intended to affect the structure or any function of the body of man" and hence is a "drug" for purposes of the FDCA.⁹³ Similarly, the administrative record made plain that cigarettes contain "device" components (*e.g.*, the blend, filter and ventilation system) that are designed to release tobacco smoke delivering a controlled amount of nicotine to the brain.⁹⁴ Finally, the "drug" (nicotine) and the "device" (the cigarette) comprise a "combination" product subject to FDA jurisdiction under the FDCA.⁹⁵

89. *Id.*

90. *Id.*

91. *Id.* at 44,812-13.

92. *Id.* at 45,233.

93. *Id.* at 45,207, *et seq.*

94. *Id.* at 45,208, *et seq.*

95. *Id.* Similar conclusions apply with respect to smokeless tobacco. Processed tobacco in smokeless products delivers nicotine
(Cont'd)

Although subjecting tobacco products to regulation, the FDA deferred consideration of discrete questions more properly addressed during a classification proceeding — such as the imposition of controls that would result in a "reasonable assurance of safety and effectiveness" for the use of tobacco products:

It would not be appropriate for FDA to make a final determination at this time as to whether the application of all appropriate regulatory controls identified in a classification proceeding would result in a reasonable assurance of safety and effectiveness for cigarettes and smokeless tobacco for any users. This determination must await completion of the classification process and of any regulatory steps identified in the classification process⁹⁶

(Cont'd)

to the cheek and gum tissue for absorption; porous pouches also used in smokeless products hold processed tobacco in the mouth, controlling the absorption of nicotine. *Id.* at 45,213-14. Accordingly, smokeless tobacco products are "combination" products containing device components that deliver nicotine to the body. *Id.*

96. *Id.* at 44,412; *see also* 21 U.S.C. § 360c. The FDA's determination is made by "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use," 21 U.S.C. § 360c(a)(2)(C) — a standard "predicated upon the recognition that no regulatory mechanism can guarantee that a product will never cause injury" because "[r]egulation cannot eliminate all risks but rather must eliminate those risks which are unreasonable in relation to the benefits derived." H.R. Rep. No. 853, 94th Cong., 2d Sess., at 16-17 (1976).

4. Focus on Youth

In deciding upon appropriate regulatory steps at this time, the FDA was particularly swayed by evidence that nicotine addiction is a "pediatric disease." The evidence before the FDA demonstrated that despite a decline in smoking in most segments of the adult population, the incidence of tobacco use among youth had increased significantly to more than 4 million persons.⁹⁷ Moreover, the evidence left no doubt that an overwhelming proportion of adolescents regret their decision to smoke, two-thirds saying they want to stop but find it difficult to do so.⁹⁸ If left unchecked, this nicotine addiction will continue into adulthood, as evidenced by the fact that more than 80% of adults who ever smoked had their first cigarette before the age of 18, and more than half of these adults had already become regular smokers by that age.⁹⁹ The FDA found obvious implications for public health:

the earlier a young person's smoking habit begins, the more likely he or she will become a heavy smoker and therefore suffer a greater risk of diseases caused by smoking. Approximately one out of every three young people who become regular smokers each day will die prematurely as a result

As long as children and adolescents become addicted to cigarette and smokeless tobacco use . . . there is little chance that society will be able [to] reduce the toll of tobacco-related illnesses. If, however, the number of children and adolescents

97. 61 Fed. Reg. at 44,398.

98. *Id.*

99. *Id.*

who begin tobacco use can be substantially diminished, tobacco-related illness can be correspondingly reduced because . . . anyone who does not begin smoking in childhood or adolescence is unlikely to ever begin.¹⁰⁰

To discharge its obligations under the FDCA, the FDA carefully tailored regulations to target adolescent smoking. Among other things, the regulations prohibit the sale of tobacco products to persons under the age of 18 and require retailers to verify the age of purchasers.¹⁰¹ In addition, the regulations limit young people's access to tobacco by prohibiting free samples and the sale of products through vending machines and self-service displays except where adolescents are not present.¹⁰² Finally, the regulations limit advertising to which children are exposed to black-and-white, text-only format, prohibit outdoor advertising within 1,000 feet of playgrounds and schools and prohibit sponsorship of sporting and other events by use of a brand name of a tobacco product.¹⁰³

The FDA's determination that tobacco products are subject to regulation under the FDCA was not only a "permissible"¹⁰⁴ construction of the statute but indeed compelled by the scientific evidence amassed during the administrative proceedings and by the tobacco industry's recently-discovered

100. *Id.* at 44,399.

101. *Id.* at 44,616, *et seq.*

102. *Id.*

103. *Id.*

104. *Chevron U.S.A. v. Natural Resources Defense Council*, 467 U.S. at 843.

internal documents. The FDA's assertion of jurisdiction is not, as the tobacco industry has contended, a "change of position" designed to override Congressional will but rather a reasoned response to a new scientific consensus. In attempting to curb nicotine addiction at its source — by reducing adolescent smoking — the FDA has fulfilled its responsibility under the FDCA to protect "the lives and health of people which . . . are largely beyond self-protection."¹⁰⁵

105. *Dotterweich*, 320 U.S. at 280.

CONCLUSION

For all the foregoing reasons, the decision of the Court of Appeals should be reversed.

Respectfully submitted,

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No. 98-1152

In The
Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, ET AL.,
Petitioners,

v.

BROWN AND WILLIAMSON TOBACCO CORP., ET AL.,
Respondents.

On Writ Of Certiorari To The
United States Court Of Appeals
For The Fourth Circuit

**BRIEF AMICUS CURIAE
OF ACTION ON SMOKING AND HEALTH (ASH)
IN SUPPORT OF PETITIONERS**

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INTEREST OF AMICUS CURIAE¹

Amicus Curiae, Action on Smoking and Health (ASH), is the oldest and largest anti-smoking organiza-
tion in the country dedicated solely to the issues of
tobacco and smoking. It is also the organization responsi-
ble for the D.C. Circuit's decision in *ASH v. Harris*, 655
F.2d 236 (D.C. Cir. 1980) ("ASH"), which first enunciated
that the FDA could determine that it had authority to
regulate cigarettes if new evidence justified a departure
from its prior position. In ASH's view, that decision has
been misconstrued in the Fourth Circuit's majority opin-
ion (hereinafter the "Fourth Circuit").

ASH is a national non-profit scientific and educa-
tional organization which for over 30 years has focused
on the problems of tobacco. ASH and its Executive Direc-
tor, John F. Banzhaf III, have brought many legal actions
related to smoking, including *Banzhaf v. FCC*, 405 F.2d
1082 (D.C. Cir. 1968) (upholding FCC ruling that televi-
sion and radio stations must provide substantial free time
for anti-smoking messages); *Capital Broadcasting Co. v.*
Mitchell, 333 F.Supp. 582 (D.C. Cir. 1971), *aff'd*, 405 U.S.
1000 (1972) (upholding the Congressional ban on ciga-
rette commercials); *National Ass'n of Motor Bus Owners v.*
United States, 370 F.Supp. 408 (D.D.C. 1974) (upholding
ICC regulation restricting smoking on buses); and, *ASH v.*
CAB, 699 F.2d 1209 (D.C. Cir. 1983) (requiring former
Civil Aeronautics Board to adopt reasonable regulations
for non-smoking sections on airplanes).

¹ John F. Banzhaf III, Chief Counsel and Kathleen E. Scheg,
Legislative Counsel authored the brief for ASH. No counsel for
either party authored the brief in whole or in part and no one
apart from ASH's donor members made a monetary
contribution to the preparation or submission of this brief.

Consent to the filing of this brief has been granted by the
parties. Their letters of consent are attached.

ASH has a special interest in the instant case because over 20 years ago, in 1977, Action on Smoking and Health petitioned the FDA to regulate tobacco products as "drugs". In 1978, ASH again petitioned the FDA to regulate cigarettes, this time as "devices," under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.* These petitions led to the decision of the D.C. Circuit in *ASH* which held that the FDA could consider so-called "extrinsic evidence" to determine manufacturers' "intent" that nicotine is an addictive drug.

Underlying the legal issues presented in this case is the source of the leading preventable cause of death, disease and disability in the Nation. Each year cigarette smoking kills more than 400,000 American smokers – more than alcohol, motor vehicles, AIDS, crime, and illegal drugs *combined!* – and costs the American economy over \$100 billion.

During the past several years there has been an explosive increase in smoking among teens – approximately 3,000 try it for the first time every single day, and approximately half become addicted – exactly the problem towards which the FDA's regulations are addressed. There is no more important public health issue, and the authority of the FDA to regulate tobacco products will affect millions of people – most of them now children – well into the next millennium.

SUMMARY OF ARGUMENT

Under *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984) ("*Chevron*"), the Fourth Circuit should have deferred to the FDA's interpretation of its statute because Congress has not clearly addressed the precise issue of the agency's jurisdiction over cigarettes. Instead, the Fourth Circuit suggests, incorrectly, that *Chevron* does not apply to issues of an agency's jurisdiction; that Congressional inaction many

years ago is more decisive on this issue than two recently-passed statutes which deal directly with it; and that the Fourth Circuit's disagreement with the agency's decisions regarding matters of policy and how best to regulate cigarettes provides a justification for avoiding *Chevron*.

Alternatively, the FDA's decision should be upheld because it simply applied an accepted definition of a statutory term as upheld in the *ASH* case, and applied it to newly-discovered but long-concealed evidence of manufacturers' intent which is a sufficient prerequisite for jurisdiction. The need for agencies to reevaluate prior decisions, especially in light of new evidence, has long been established, and the *ASH* court, faced with virtually the same legislative history as the Fourth Circuit, expressly recognized the need regarding this issue.

To the extent that legislative history is relevant, Congress' refusal to head off the FDA's widely-announced plans to regulate cigarettes or to limit the regulations once adopted – as it has done in many other situations – negates any idea of a clear and precise intent regarding this issue. Moreover, in two recent statutory enactments, Congress has made it clear that it is not opposed to FDA regulation of cigarettes under the existing act – a precondition for avoiding the application of *Chevron* to the FDA's determination.

The Supreme Court should reverse the instant decision and, in remanding, permit the FDA's regulations to become effective pending any further proceedings. The public interest in protecting approximately 3000 children a day from becoming addicted to nicotine far outweighs the industry's interest in avoiding regulations more modest than those imposed on most other drug makers; most of which they had agreed to as part of a proposed (but failed) national tobacco settlement.

ARGUMENT

I. THE FDA'S INTERPRETATION OF ITS STATUTE MUST BE DEFERRED TO UNDER THE *CHEVRON* DOCTRINE BECAUSE CONGRESS HAS NOT SPOKEN DIRECTLY TO THE PRECISE QUESTION AT ISSUE, AND FOLLOWING REPEATED REQUESTS THAT IT DO SO, CONGRESS THEN EXPRESSLY DECLINED TO ADDRESS THE LEGAL ISSUE OF THE FDA'S JURISDICTION OVER TOBACCO

In the instant case, the Fourth Circuit erred in not deferring to the Federal Food and Drug Administration (FDA)'s interpretation of the Food Drug and Cosmetic Act (FDCA), 21 U.S.C. 321 *et seq.*, and to FDA's expert assessment as to the impact of previously secret tobacco-industry documents, the first of which were uncovered after 1990 and therefore not previously available for consideration by Congress or the agency prior to then.

Under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), courts should defer to permissible agency interpretations of statutory terms unless the intent of Congress on the issue has been clearly and precisely stated. In reviewing an agency's construction of a statute such as the Food, Drug and Cosmetic Act, §§ 201(g)(i)(c),(h)(3), 520(e), as amended, 21 U.S.C. §§ 321(g)(i)(c),(h)(3) 360(e), *Chevron* requires a two-step analysis.

The first step is to determine whether Congress has spoken *directly* to the precise question at issue. When Congress has not directly addressed the precise question at issue, then, under *Chevron*, the second step is for the court to determine if the agency's interpretation is a permissible construction of its statute. *Chevron* at 842-43.²

² The Fourth Circuit's conclusion that the *Chevron* analysis does not apply where the underlying issue is the agency's jurisdiction seems inconsistent with this Court's precedents.

A. After Virtually Conceding That Congress Had Never Directly Addressed the Issue of the FDA's Jurisdiction Over Tobacco, the Fourth Circuit Cited Dubious Indicia of "Congressional Intent" – Most Largely Irrelevant Because They Occurred Before the Crucial Evidence Was Uncovered – to Justify Substituting Its Own Judgment for that of the FDA

The first issue, under *Chevron*, is whether Congress has *directly* spoken on the *precise* question at issue.

"The Commission now argues explicitly in favor of *Chevron* deference; Oklahoma Natural Gas resists, on the ground that deference is inappropriate for jurisdictional issues. Although not directly ruling upon the matter of deference on such issues, the Supreme Court has in practice deferred even on jurisdictional issues. See *Reiter v. Cooper*, 507 U.S. 258, ___, 113 S.Ct. 1213, 1221, 122 L.Ed.2d 604 (1993) (applying *Chevron* to ICC's determination that statute did not grant it 'initial jurisdiction . . . with respect to the award of reparations'); *Commodity Futures Trading Comm'n v. Schor*, 478 U.S. 833, 844-45, 106 S.Ct. 3245, 3253, 92 L.Ed.2d 675 (1986) (applying *Chevron* to scope of the Commission's jurisdiction over counterclaims); *NLRB v. City Disposal Systems, Inc.*, 465 U.S. 822, 830 n. 7, 104 S.Ct. 1505, 1510 n. 7, 79 L.Ed.2d 839 (1984) (pre-*Chevron* decision expressly rejecting proposition that a different level of deference guides review of 'a jurisdictional or legal question concerning the coverage of the National Labor Relations Act'). See generally, Comment, *Chevron Deference to Agency Interpretations that Delimit the Scope of the Agency's Jurisdiction*, 61 U.Chi.L.Rev. (1994). So have we.' *Oklahoma Natural Gas Co. v. Federal Energy Regulatory Commission*, 28 F.3d 1281, 1283 (D.C. Cir. 1994)."

Moreover just last year, in *Bragdon v. Abbott*, 524 U.S. 624 (1998), this Court held that HIV infection is a "disability" under the ADA, based in part upon regulations promulgated by the U.S. Department of Justice which is charged by law with enforcing Title III of the ADA in court – thereby expanding its jurisdiction to cover this condition.

Chevron at 842. The precise question at issue here is whether the FDA has authority to regulate cigarettes as "drugs" or as "devices" under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 321 *et seq.*, absent certain claims. Neither respondents nor the Fourth Circuit has shown any instance in which Congress has directly spoken on the issue of the FDA's authority to regulate tobacco products as drugs and devices under the FDCA. This is because Congress has never directly spoken on that issue.

Rather, the Fourth Circuit attempts to circumvent the first step in the *Chevron* doctrine by instead entering into a convoluted analysis of Congressional intent despite "as much as conceding that tobacco products fit the FDA's 'literal' definition of a drug," *Brown and Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 175 (4th Cir. 1998) ("*Brown*") and that "[a] mechanical reading of only the definitions provisions may appear to support the government's position that tobacco products fit within the Act's definitions of drugs and devices."³ *Id.* at 163.

The Fourth Circuit entered into this convoluted analysis of Congressional intent because it could not find a direct Congressional statement denying the FDA authority to regulate tobacco products – similar to those Congress expressly included in so many other statutes, see discussion *infra*, part III. B. – because no such congressional denial of FDA authority exists.

³ The Fourth Circuit's decision to overturn the FDA's conclusion that it had jurisdiction, even after apparently concluding that cigarettes containing nicotine meet the statutory definition, also seems to fly in the face of *United States v. Bacto-Unidisk*, 394 U.S. 784 (1969). There this Court said "that Congress fully intended that the Act's coverage be as broad as its literal language indicates and equally clearly, broader than any strict medical definition might otherwise allow." *Id.* at 798 [emphasis added].

In fact, when the issue was very recently and directly before Congress in the "Food and Drug Administration Modernization Act of 1997", Public Law 105-115, sec.422 (Nov. 21, 1997), Congress deliberately chose not to address it, but rather to maintain the status quo and defer to whatever authority the FDA had under the FDCA. See discussion *infra*, part III. C. The *Chevron* doctrine is clear. To stop the *Chevron* analysis at step one, and to permit a court to override the judgment of an agency, there must be an unambiguous expression of Congressional intent on the precise issue. Here, as the Fourth Circuit concedes, there is none.

Instead, and in its place, the Fourth Circuit seeks to substitute a catalog of statements by the FDA to Congress, and Congress' non-action regarding regulation of tobacco by the FDA, as so-called evidence of a Congressional determination that the FDA does not have jurisdiction. However, virtually all of these events are irrelevant because they occurred prior to the time key evidence was uncovered.

As both the *Brown* court and the *ASH* court noted, a key and necessary element to finding jurisdiction over a "drug" or "device" in this context is the intent of the manufacturer. [*Brown*, 153 F.3d at 17, *ASH*, 655 F.2d at 10-11]

In other words, it is not enough that the substance "affect the structure or any function of the body." It must also be the intent of the manufacturers that it do so.⁴ But

⁴ Without this second part of the definition, substances like house paint, paint thinner, airplane glue, and other common products could be considered "drugs" because they do in fact affect the functioning of the body when inhaled (*i.e.*, create a "high" manifested by marked changes in pulse rate, blood pressure, etc.). However, since there is no evidence that the manufacturers intend such a use, or that most purchasers use the product to create such effects (from which such an intent

the evidence that cigarette manufacturers knew of nicotine's addictive and other drug effect properties, and – through manipulation of nicotine levels and pH levels, cultivation of high-nicotine plants, and other means – intended these effects, were kept secret by the industry.

Since the recently disclosed documents are a key element of the definition and of the proof necessary to conclude that a substance meets the definition, the fact that prior to their discovery the FDA testified that it had no jurisdiction is irrelevant. Indeed, to allow cigarettes to continue their unique status as virtually unregulated products⁵ simply because their makers concealed evidence of their intent from the FDA, Congress, and others, would be to permit them to profit from their wrongdoing.

As Joseph A. Califano, Jr., former U.S. Secretary of Health, Education, and Welfare, testified before the House Energy and Commerce Committee's Subcommittee on Health, May 17, 1994, this previously hidden information would have altered the FDA's regulatory posture.

The evasions, lies, and transfer of documents overseas by the tobacco industry to prevent any Government agency or cigarette-injured patient from finding them has distorted U.S. Government policy for 30 years.

Had we known what the tobacco companies knew and had we been privy to their research on the addictive nature of nicotine and their ability to manipulate the amount of nicotine in cigarettes, the 1979 Surgeon General's report would have found cigarettes addictive and we

might be inferred using the second prong of the *ASH* test), they are not "drugs."

⁵ Although cigarettes are regulated for tax purposes, and the FTC has jurisdiction over their advertising, cigarettes are virtually the only consumer product not substantively regulated by the Consumer Product Safety Commission or any other agency.

would have moved to regulate them. Unfortunately, the President of the United States, the Secretary of Health, Education, and Welfare, and the Surgeon General of the United States were *all victims of the concealment and disinformation campaign of the tobacco companies.* (emphasis added)

B. The Fourth Circuit Also Violated the *Chevron* Doctrine By Not Only Substituting its Policy Judgments for FDA's Reasonable Determinations, But By Using Its Own Judgments as Evidence of Congressional Intent

The *Chevron* doctrine requires deference to the agency for a permissible construction of its statute if the statute is silent or at all ambiguous with respect to the specific issue. *Chevron* at 842-43. This is true even if the court might prefer a different construction of the statute. *Chevron* at 845. In short, a court is not permitted to substitute its policy judgments for those of the agency.

Yet, ironically, here the Fourth Circuit not only substituted its judgments as to matters of public health and policy; it sought to add those judgments to its recitations of irrelevant Congressional history to circumvent the first prong of the *Chevron* test.

As further so-called evidence that Congress' intent that the FDA has no jurisdiction over tobacco is clear and unambiguous, the Fourth Circuit cites as what it calls "Intrinsic Evidence" various determinations which the agency has made regarding cigarettes under its statute. It criticizes the agency for:

★ concluding "that withdrawal of tobacco from the market poses significant health risks to addicted adults which outweighs the risks of leaving tobacco products on the market";

★ characterizing "tobacco products as combination products containing drug and device components";

- ★ "exempting tobacco products under § 352(f) without any assurances of safety";
- ★ failing to require cigarettes to bear "adequate warnings against use . . . by children where its use may be dangerous to health";
- ★ improperly choosing the category for regulating cigarette as medical devices;
- ★ deciding not to issue an immediate cease distribution order for all such tobacco products.

But these determinations – how best to protect the public health from a product to which tens of millions of people are already addicted – are exactly the kind of decisions Congress wished to place initially in the hands of an agency with specific expertise in this area, and the ability to conduct and evaluate studies, seek out experts, invite a wide range of public opinion, etc. These, of course, are exactly the capabilities the courts – including the Fourth Circuit – lack.⁶

⁶ The FDA meticulously addressed each of these issues in its decision – using not only its expertise and experience, but also the policy-making power Congress delegated to it – to determine the most appropriate remedies and regulation for a unique product to which approximately 50 million Americans are already addicted, and where congressionally-mandated health warnings already appear.

As this Court noted in *Chevron*, "[t]he arguments over policy that are advanced in the parties' briefs create the impression that respondents are now waging in a judicial forum a specific policy battle which they ultimately lost in the agency. . . . Such policy arguments are more properly addressed to legislators or administrators, not to judges." 467 U.S. at 864. [emphasis added]

Here it appears that the Fourth Circuit is likely seeking not only to review these complex policy determinations in the judicial forum, but to use their disagreement with the agency's policy determination as a basis to avoid complying with *Chevron*.

Applying *Chevron* to permit agencies latitude to decide questions which Congress has not precisely and definitively addressed does not, of course, mean that the agency will have the last word, or that only the courts can correct inappropriate use of regulatory authority.

For example, when the FDA initially determined that vitamins and other dietary supplements met certain regulatory requirements and Congress disagreed, it passed the Dietary Supplement Health and Educational Act of 1994, Public Law 103-417. This substantially limited the FDA's authority, and adopted standards which Congress believed were more appropriate to the problem.⁷

Similarly, when it was held that the Consumer Product Safety Commission (CPSC) had jurisdiction over so-called "high tar" cigarettes, Congress reacted by passing, within only 60 days, a statute removing this jurisdiction. See generally, *ASH* at 18.

Thus, if Congress decides in the future that the FDA should not regulate cigarettes, or that it should regulate them in ways other than it has chosen to do, Congress is certainly free to act in this instance as it did with dietary supplements or the CPSC.

II. THE FDA'S INTERPRETATION OF ITS STATUTE HAS NOT CHANGED – IT HAS SIMPLY APPLIED THE EXISTING STATUTORY TEST, ONE ALREADY CONFIRMED BY THE *ASH* DECISION, TO NEWLY DISCOVERED EVIDENCE OF MANUFACTURERS' INTENT

In the alternative, it is respectfully suggested that the situation can also be analyzed as one in which the agency didn't so much reinterpret a statutory term as it applied

⁷ Comment, Melatonin Mania: Can the FDA Regulate Hormonal Dietary Supplements to Protect Consumer Interests in Light of the Dietary Supplement Health and Education Act of 1994?, 22 Dayton L. Rev. 77 (1996).

an existing statutory definition to newly-discovered evidence. Thus, the statutory term(s) – the definition of a “drug” or “device” upon which the FDA relied – remained the same as that set out in the D.C.’s Circuit’s *ASH* decision. What changed was that the FDA applied it to evidence which was not known when the agency had previously testified before Congress, and when it had concluded in the *ASH* case that the evidence known at that time did not justify its regulation of cigarettes as either “drugs” or “devices.”

A. An Overwhelming Amount of New Evidence Clearly Showing That Cigarette Manufacturers Intended to Use and Even Manipulate Nicotine to Create and Maintain Addiction More Than Justified the FDA’s Reconsideration of Its Prior Position

In the instant case, there can be no doubt that there have been dramatically changed circumstances affecting the FDA’s knowledge of the drug and device properties of cigarettes. In only the past few years, reams of previously secret tobacco-industry information about its products have come to light from various sources including leaks, litigation discovery, exposure by some Members of Congress, and other sources.⁸ These include documents showing:

★ that tobacco industry executives considered nicotine to be an addictive drug, and themselves to be in the drug business

⁸ Some highlights of these documents will be found in the testimony of FDA Commissioner Dr. David Kessler before Congress on this issue, *See discussion infra* part III. A. Many of the documents relied upon are set forth in the FDA’s discussion of its regulations in 60 Fed. Reg. 41,314 (1995) and 61 Fed. Reg. 44,396 (1996).

★ that they were concerned that, if information about certain secret activities leaked out, it would provide a basis for FDA jurisdiction over cigarettes

★ that cigarette manufacturers conducted extensive-but-secret experiments confirming the addictive and other drug effect properties of nicotine, and even how to increase its addictiveness

★ that the industry developed and patented special high-nicotine tobacco plants, apparently in an effort to increase the drug effect properties of cigarettes

In the light of such evidence, it was only reasonable for the FDA to reconsider its earlier position that cigarettes do not fall within its jurisdiction because there is no evidence of manufacturers’ intent.

Indeed, by expressly incorporating a very broad and flexible statutory definition – which is of necessity based upon factual findings of issues like drug effects on the body and of manufacturers’ intent – it is clear that Congress wished the FDA to be able to revisit prior decisions in light of new evidence, rather than waiting for Congress to act on it.

B. The *ASH* Court Set the Stage For a Reevaluation by the FDA of its Cigarette-Jurisdiction Decision in Light of New Evidence Which Might Be Discovered in the Future, and Held That Such Reevaluation Would Be Appropriate and Judged by the “Arbitrary and Capricious” Standard of Review

In *ASH*, the U.S. Court of Appeals, even prior to this Court’s *Chevron* decision, used the most permissive standard to review the FDA’s determination of whether it had

jurisdiction over cigarettes as either "drugs" or "devices."⁹

Even while deferring to the FDA's decision not to regulate cigarettes as drugs or devices in 1980, the D.C. Circuit Court of Appeals foresaw that the agency might need to reconsider its position at a later date. The Court – having before it virtually the same legislative history as the Fourth Circuit, nevertheless held that:

Nothing in the opinion should suggest that the Administration is irrevocably bound by any long-standing interpretation and representations thereof to the legislative branch. An administrative agency is clearly free to revise its interpretations. See *Intl. Union, United Auto., Aero. & Agric. Implement Workers of American (UAW) v. NLRB*, 148 U.S. App. D.C. 305, 459 F.2d 1329, 1344 (D.C. Cir. 1972). The very structure of the Act which the FDA must administer, moreover, calls for case-by-case analysis. 655 F.2d at 242 FN. 10.

Over 20 years ago, when the FDA denied ASH's petitions to have cigarettes regulated as "drugs" or "devices" under the FDCA, the FDA had already been exercising its jurisdiction over certain cigarettes, and that jurisdiction had been upheld by the courts.¹⁰

⁹ "According to the Administration's interpretation proper deference, we do not find this agency action arbitrary, capricious, or contrary to law and therefore affirm the judgment of the district court." *ASH*, 655 F.2d at 236 "The Commissioner's determination, that this is not the proper case in which some evidence of consumer use, even if demonstrating the appropriate intent, may suffice to establish the requisite statutory intent, was thus neither arbitrary nor capricious." *ASH*, 655 F.2d at 240 [emphasis added to both]

¹⁰ See, *United States v. 46 Cartons More or Less, Containing Fairfax Cigarettes*, 113 F.Supp. 336 (D.N.J. 1953), and *United States v. 354 Bulk Cartons***Trim Reducing-Aid Cigarettes*, 178 F.Supp. 847 (D.N.J. 1959).

Additionally, in recent years, the FDA has also regulated nicotine in patches, chewing gum and inhalants. Thus, it has been recognized for over 40 years that the FDA has authority over cigarettes in some situations, and over other products because they contain nicotine.

The dispute in *ASH*, therefore, was not over whether the FDA had the authority to regulate cigarettes at all but whether, at that time, the FDA had sufficient evidence of the manufacturers' "intent" to exercise that jurisdiction in the absence of specific claims.

Then Commissioner Donald Kennedy denied the petitions because at that time the FDA was focused upon the manufacturers' representations, and was only exercising its jurisdiction over cigarettes when the vendors or manufacturers made explicit health claims. He did not deem ASH's then largely-unsupported argument that some smokers used cigarettes to affect the structure and function of their bodies as sufficient in itself to justify asserting jurisdiction over cigarettes. Nor, of course, did ASH have or present any other extrinsic evidence of intent.¹¹

The door, however, was left open for further regulation of cigarettes based upon additional evidence. The court in reviewing the FDA's decision, made it clear it believed the FDA could, at a later date, consider evidence of consumer intent, along with other relevant evidence:

¹¹ Now, however, the picture has completely changed. New evidence from previously-secret tobacco documents shows that most cigarette users smoke because of the changes which nicotine produces in their bodies.

Moreover, there is now abundant "extrinsic evidence" that manufacturers intend these drug-like effects to occur. Not only do they carefully study them and discuss cigarettes as nicotine-delivery devices; they also use various practices to enhance the nicotine actually delivered to the smoker and to make it more addictive (e.g., by adjusting pH levels).

[W]e do not read these statements to mean either that the Commissioner will never consider evidence of consumer intent on this question. Rather, by failing to introduce any evidence of vendors' intent – whether based on subjective vendor claims or *objective evidence* such as labeling, promotional materials, and advertising – ASH placed itself in the position of having to meet the high standard established in cases where the statutory 'intent' is derived *from consumer use alone*. Clearly, it is well established 'that the "intended use" of a product, within the meaning of the Act, is determined from its label, accompanying labeling, promotional claims, advertising, and any other relevant source.' *Hanson v. United States*, 417 F.Supp. 30, 35 (D.Minn.), *aff'd*, 540 F.2d 947 (8th Cir. 1976). Whether evidence of consumer intent is a 'relevant source' for these purposes depends upon whether such evidence is strong enough to justify an inference as to the vendors' intent. (emphasis added) *ASH*, 655 F.2d at 239

Most significantly, the Court, citing Judge Friendly in an analogous situation, went on to state that "we agree that a factfinder should be free to pierce all of a manufacturer's subjective claims for intent and even his misleading labels to find actual therapeutic intent on the basis of objective evidence in a proper case. . . . " *Id* at 239, citing *National Nutritional Foods Association v. Food & Drug Administration*, 504 F.2d 761, 789 (2d Cir. 1974) (high-dosage vitamin products not per se therapeutic), *cert. denied*, 420 U.S. 946, 95 S.Ct. 1326, 43 L.Ed.2d 424 (1975).

It is hard to imagine a more appropriate case than this one justifying the FDA's decision to pierce the manufacturers' subjective claims of intent. The information that has been uncovered in the last few years from previously secret tobacco industry documents shows over and over again that the tobacco industry knew and intended its

cigarettes to "affect the function and structure of the body"; they also intended to deceive the public and the FDA by denying publicly what they knew internally.

The information about the manufacturers' true intent having not been originally publicly disclosed or made available to the FDA, it was appropriate for the FDA to reevaluate its decision to regulate cigarettes when the new evidence became available. It is new evidence, not a change in the underlying authority of the FDA, that led to the regulations under review. For almost 50 years, the FDA has regulated cigarettes and other nicotine products when it has had sufficient evidence of the manufacturers' intent to "affect the structure and function of the body." It now has that information, and the regulations under review are the result.

As former Secretary Califano indicated, had this information been available earlier, the FDA could have moved to regulate cigarettes then. It is only the tobacco manufacturers' concealment of the relevant information that has prevented the FDA from protecting the public by regulating cigarettes. Such corporate deceit cannot be sanctioned, much less rewarded – as it would be if the FDA's jurisdiction is overturned simply because Congress and the agency were deceived about the drug effects of nicotine and the manufacturers' intent regarding it.

C. In any Event, Courts Have Always Held That Agencies Have the Flexibility to Review and Revise Their Interpretations and Other Determinations, and That Such Determinations Must be Given Deference

Under the *Chevron* doctrine, a revised agency interpretation deserves deference. "An initial agency interpretation is not instantly carved in stone." *Chevron* at 863. Rather particularly "in the context of implementing policy decisions in a technical and complex arena. . . . the agency, to engage in informed rulemaking, must consider

varying interpretations and the wisdom of its policy on a continuing basis." *Id* at 863-64; *Rust v. Sullivan*, 500 U.S. 173, 186 (1991).

As stated in *Rust*, changing circumstances necessitate an agency revising its statutory interpretation. *Rust* at 186-187 citing *Motor Vehicle Mfrs. Assoc. of United States, Inc. v. State Farm Mut. Auto. Ins. Cos.*, 463 U.S. 29, 42, quoting *Permian Basin Area Rate Cases*, 390 U.S. 747, 784 (1968).

D. Alternatively, FDA Authority To Regulate Cigarettes Is Justified Even Viewed As A Revised Interpretation Of Its Statute

Chevron, the leading case on deference to an agency's interpretation of its own statute, was itself a case involving a revised interpretation of a statute. The Court there stated:

The fact that the agency has from time to time changed its interpretation . . . does not . . . lead us to conclude that no deference should be accorded the agency's interpretation of the statute. An initial agency interpretation is not instantly carved in stone. On the contrary, the agency, to engage informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis. *Chevron*, 467 U.S. at 863-64 (emphasis added)

Rather, an agency such as the U.S. Department of Health and Human Services "must be given ample latitude to 'adapt (its) rules and policies to the demands of changing circumstances.'" *Rust*, 500 U.S. at 187, citing *Motor Vehicle Mfrs. Assoc.*, 463 U.S. at 42 (1983).

There can be no doubt that circumstances have changed dramatically in regard to tobacco products in the last few years. As discussed more fully, *infra*, the change was so dramatic that then FDA Commissioner Kessler spent two days testifying before Congress on the new

revelations. Even in the three months that elapsed between those two Congressional dates, substantial new information became available.

III. TO THE EXTENT THAT LEGISLATIVE HISTORY IS RELEVANT UNDER *CHEVRON*, IT DEMONSTRATES THAT CONGRESS HAS NOT CONCLUSIVELY DECIDED THAT THE FDA SHOULD NOT REGULATE CIGARETTES; INDEED, TWO RECENT STATUTORY ENACTMENTS EXPRESSLY SET FORTH THAT PRECISE DETERMINATION

ASH contends that the FDA's jurisdiction to regulate tobacco products can be upheld based on deference to the FDA's interpretation of its own statute under *Chevron* and other decisions, and that there is no need to look to so-called "extrinsic evidence" (e.g., Congressional inaction) as the Fourth Circuit did. However, a review of Congressional intent actually supports FDA regulation of tobacco products.

The Fourth Circuit erroneously relies on historical inaction by the FDA – and in particular the agency's refusal in *ASH* to assert its jurisdiction over tobacco products – as a basis for finding that Congress didn't intend to give the FDA authority over tobacco products. Contrary to the suggestion that *ASH* supports the Fourth Circuit opinion, that case actually provides the foundation for the FDA's decision to regulate tobacco products by making it clear that the agency could, if it wished, consider extrinsic evidence (including user intent) to infer the legislatively required intent of cigarette manufacturers.

Now an abundance of new information has come to light in recent years through the release of tens of thousands of previously secret tobacco industry documents, a number of which clearly show that tobacco products meet the statutory definition of "drugs" or "devices", 21 U.S.C.

§ 321(g)(1)(C) and (h)(3), and that the tobacco industry has known this for years and withheld the information from the public.

These previously secret tobacco industry documents provided substantial new facts on which the FDA could reevaluate its decision to regulate tobacco products. As Judge Hall recognized in his dissent:

It is a familiar canon of administrative law that an agency can change its view of what action is possible or necessary, particularly when new facts come to light. *See Rust v. Sullivan*, 500 U.S. 173, 186-87 (1991) ("An agency . . . must be given latitude to adapt its rules and policies to the demands of changing circumstances") (citations and internal quotation marks omitted). Even when upholding the FDA's earlier denial of its own power to regulate tobacco, the court (U.S. Court of Appeals, District of Columbia Circuit) added the following caveat:

Nothing in this opinion should suggest that the [FDA] is irrevocably bound by any long-standing interpretation and representations thereof to the legislative branch. An administrative agency is clearly free to revise its interpretations. . . . The very structure of the [FDCA] which the FDA must administer, moreover, calls for case-by-case analysis. Should an agency depart from its prior interpretations, however, it must provide a reasoned explanation for its action. . . . *ASH*, 655 F.2d at 242 n.10 [citations omitted].

Despite acknowledging "the general reluctance of courts to rely on congressional inaction as a basis for statutory interpretation, *see Brecht v. Abrahamson*, 507 U.S. 619, 632 (1993) (noting that "[a]s a general matter, 'we are reluctant to draw inferences from Congress' failure to act' ") (quoting *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 306 (1988)), *Brown* at 170, the Fourth Circuit then

interprets Congress' failure to enact legislation specifically granting the FDA jurisdiction over tobacco products as legislative acquiescence in FDA's earlier decision not to regulate tobacco. Yet, certainly more significant than congressional inaction during the years when the tobacco companies concealed the relevant information about the addictive properties of nicotine and their manipulation of the drug from Congress and the public at large, thereby providing Congress with no basis for action, is the Congressional inaction in light of the FDA regulations on tobacco currently under review.

A. Even After Congress Was Repeatedly Warned That New Evidence Would Require FDA Regulation of Cigarettes, and the FDA Did in Fact Move Towards Such Regulations And Eventually Adopted Them, Congress Took No Action – A Strong Indication That There Was No Established Consensus Against That Regulation

In 1994, then FDA Commissioner Dr. David Kessler appeared formally before Congress twice to warn that this newly discovered evidence would probably lead to FDA regulation of cigarettes.

On March 25, 1994, more than a year before the proposed regulations were published and over two years before the regulations became final, Commissioner Kessler testified before the House Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives, specifically on the subject of "Regulating Cigarettes".¹²

¹² Hearings on Regulating Cigarettes Before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, 103rd Cong., 2nd Sess. (1994) (statement of David A. Kessler, M.D., Commissioner, Food and Drug Administration).

He pointedly notified Congress that the FDA was seriously addressing the question of "whether nicotine-containing cigarettes should be regulated as drugs" due in large part to the mounting evidence, which had not previously been available to the FDA, that tobacco products were intended to affect the structure or function of the human body. Commissioner Kessler informed Congress that:

Although FDA has long recognized that the nicotine in tobacco produces drug-like effects, we never stepped in to regulate most tobacco products as drugs. *One of the obstacles has been a legal one.* A product is subject to regulation as a drug based primarily on its intended use. Generally, there must be an intent that the product be used either in relation to a disease or to affect the structure or function of the body. *With certain exceptions, we have not had sufficient evidence of such intent with regard to nicotine in tobacco products.*

Mr. Chairman, *we now have cause to reconsider this historical view. The question now before us all is whether nicotine-containing cigarettes should be regulated as drugs. . . . This question arises today because of an accumulation of information in recent months and years.* (emphasis added)

In that testimony, Commissioner Kessler was clearly alerting Congress to the dramatically changing circumstances which were prompting the FDA to consider regulating cigarettes. He informed Congress that:

I do not have all the facts or all the answers today. The picture is still incomplete. But from a number of pieces of information, from a number of sources, a picture of tobacco company practices is beginning to emerge. . . . *Some of today's cigarettes may, in fact, qualify as high technology nicotine delivery systems that deliver nicotine in*

precisely calculated quantities. . . . (emphasis added)

He concluded by telling Congress that "[t]he next task facing the FDA is to determine whether nicotine-containing cigarettes are 'drugs' within the meaning of the Federal Food, Drug, and Cosmetic Act." (emphasis added) He then went on to specifically ask Congress for guidance on some of the broader social issues that could arise from the FDA's regulation of cigarettes. He told the Committee:

It is important to note that the *possibility of FDA exerting jurisdiction over cigarettes* raises many broader public health and social issues for Congress to contemplate. There is the possibility that *regulation of the nicotine in cigarettes as drugs* would result in the removal of nicotine-containing cigarettes from the market, limiting the amount of nicotine in cigarettes to levels that are not addictive, or otherwise restricting access to them, unless the industry could show that nicotine containing cigarettes are safe and effective. If nicotine were removed, the nation would face a host of issues involving the withdrawal from addiction that would be experienced by millions of Americans who smoke. (emphasis added)

Then on June 21, 1994, Commissioner Kessler returned to testify before the Subcommittee on Health and the Environment.¹³ The newly discovered information that ultimately led to the FDA's regulation of cigarettes had increased significantly in only three months. In relevant part, Commissioner Kessler stated:

In my last appearance before this subcommittee on March 25, 1994, I raised the question of whether

¹³ Hearings on Regulating Tobacco Products Before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, 103rd Cong., 2nd Sess. (1994) (statement of David A. Kessler, Commissioner, M.D., Food and Drug Administration).

the Food and Drug Administration should regulate nicotine-containing cigarettes as drugs under the Federal Food, Drug, and Cosmetic Act. . . . The information that I presented about industry control and manipulation of nicotine the last time I testified before you was suggestive. Today I am going to provide you with actual instances of control and manipulation of nicotine by some in the tobacco industry that have been uncovered through painstaking investigational work over the last three months. (emphasis added)

Referring to some of these studies, Commissioner Kessler was explicit in notifying the Committee that the FDA considered them *"relevant to the determination of whether nicotine-containing cigarettes are drugs for purposes of the Federal Food, Drug, and Cosmetic Act."* (emphasis added)

In these most newsworthy remarks, Commissioner Kessler was clearly telling Congress that the newly-discovered evidence about the addictive nature of nicotine, and cigarette maker's knowledge of this property and their efforts to manipulate it, would force the FDA to regulate nicotine in cigarettes – as it has long regulated nicotine in other forms (e.g., in patches, chewing gum, and inhalants). Most telling of all, however, was his final comment regarding the blatant admission found in a tobacco industry document showing that the industry had known for many years that cigarettes were drugs. A memorandum by Brown & Williamson's then General Counsel Addison Yeaman stated: *"We are, then, in the business of selling nicotine, an addictive drug. . . ."*¹⁴

¹⁴ Addison Yeaman, "Implications of Battelle Hippo I & II and the Griffith Filter," 1963, quoted in John Slade et al., "Nicotine and Addiction: The Brown and Williamson Documents," J.Am.Med. Ass'n, Vol. 274, No. 3, pp. 225-33, July 19, 1995 (emphasis added).

Those widely-reported hearings were held more than five years ago. Congress was thus clearly on notice that the FDA was diligently advancing toward regulation of cigarettes under the Federal Food, Drug and Cosmetic Act, and yet it took no action in view of the virtual certainty of such regulation.

Indeed, even after the President's televised announcement on August 10, 1995 that the FDA was going to regulate cigarettes, the publication of a notice of proposed rulemaking to that effect on August 11, 1995 [60 Fed. Reg. 41,314], the publication of the final regulations on August 28, 1996 [61 Fed. Reg. 44,396], and numerous media reports that the rules requiring photo ID cards to purchase cigarettes had gone into effect, there has been no serious Congressional attempt to remove FDA's authority to regulate tobacco products, an indication surely of legislative acquiescence not only in FDA's authority generally to regulate tobacco products, but specifically an acceptance of the particular and limited FDA regulations for tobacco products now before the Court.

B. The Fact That Congress Has Frequently Passed Statutes Prohibiting the Regulation of Cigarettes By Other Agencies, But Has Declined – As Recently as 1994 – To Do So Regarding the FDA, Strongly Suggests That Congress Does Not Disagree With the FDA's Decision

Additionally, it is instructive to note that Congress has often excluded tobacco products from other federal laws, and obviously could have done so with the Food, Drug and Cosmetic Act. Federal laws which specifically excluded tobacco products include, for example:

1. *Federal Hazardous Substances Act*: Under the heading "definitions", the Federal Hazardous Substance Act specifies that the term "hazardous substance" does not

include "tobacco and tobacco products" sec.2(f)(2). Pub.L. No. 86-613, signed July 12, 1960.

2. *Fair Packaging And Labeling Act*: Under the heading "definitions", the Fair Packaging and Labeling Act specifies that the term "consumer commodity" does not include "any . . . tobacco or tobacco product" sec.10(a)(1), Pub.L. No. 89-755, signed November 3, 1966.

3. *Consumer Product Safety Act*: Under the heading "definitions", the Consumer Product Safety Act specifies that the term "consumer product" does not include "tobacco and tobacco products." sec.3(a)(1)(B), Pub.L. No. 92-573, signed October 27, 1972.

4. *Toxic Substances Control Act*: Under the heading "definitions", the Toxic Substance Control Act specifies that the term "chemical substances" does not include "tobacco or any tobacco product." sec.3(2)(B)(iii), Pub.L. No. 94-469, signed October 11, 1976.

Most significantly, as recently as 1994, Congress explicitly excluded tobacco from the jurisdiction of the FDA, but only under the "dietary supplements" exemption from the definitions of a "drug" in the FDCA itself.¹⁵ Clearly, Congress could have excluded tobacco entirely from the coverage of the FDCA at the time – particularly since it was focusing on exactly the same agency, and it passed the act just months *after* then Commissioner Kessler had twice warned Congress in widely-reported testimony that the FDA was likely to regulate cigarettes as a "drug" and/or "device." Congress, however, did not.

Thus it can be argued that by excluding tobacco from the "dietary supplements" definition of the FDCA, but not at the same time dealing in any way with its proposed inclusion under other sections of the agency's act, Congress was expressing its intent to retain FDA jurisdiction over tobacco as a "drug". At the very least, it clearly

¹⁵ Pub.L. No. 103-407, sec.2(a), 108 Stat. 4325, 4327 (codified at 21 U.S.C. § 321(ff)(1)).

and unambiguously indicated that this power did not contradict the will of Congress.

C. The Most Important – and, Indeed, the Only Controlling – Evidence of Congressional Intent Regarding FDA Jurisdiction Over Cigarettes Was The Passage of Legislation Expressly Leaving the Issue Open and Unresolved

Courts are understandably very reluctant to interpret statutes – and even more reluctant to overturn an agency's own interpretation of its own statute – based upon a legislative history consisting of inaction; exactly the type of evidence the Fourth Circuit relied upon in its ruling. Far more important – and indeed, the only controlling – evidence of legislative intent occurs when Congress passes legislation which becomes law.

On November 21, 1997, more than a year after the FDA regulations governing cigarettes had become final, and some of them were already in effect, Congress passed the omnibus "Food and Drug Administration Modernization Act of 1997," Pub.L. No. 105-115 (Nov, 21, 1997) (hereinafter *Modernization Act*). Although Congress' attention was obviously focused on the FDA, and every Member of Congress undoubtedly knew of its cigarette regulations, the bill did not seek to re-define, clarify, modify, or otherwise address the issue of FDA jurisdiction over cigarettes. Instead, in a very telling move, Congress explicitly declined to take action on the question of the FDA's authority to regulate tobacco products, and deferred to whatever authority the FDA had under the FDCA, providing in relevant part:

Nothing in this Act or the amendments made by this Act shall be construed to affect the question of *whether the Secretary of Health and Human Services has any authority to regulate any tobacco product, tobacco ingredient, or tobacco additive.* Such authority, if any, shall be exercised under

the Federal Food, Drug, and Cosmetic Act as in effect on the day before the date of the enactment of this Act. (emphasis added)

As of November 20, 1997 the day before the enactment of that Act, the FDA had determined that it had jurisdiction over cigarettes and its basic jurisdiction had been upheld in *Coyne Beahm, Inc. v. FDA*, 966 F.Supp. 1374 (M.D. N.C. 1997) ("*Coyne*") which had been decided on April 25, 1997. Although *Coyne* was subsequently reversed in the instant case on August 14, 1998, *Coyne* governed on November 20, 1997. The *Coyne* decision had been widely publicized so there can be no doubt that Congress would have been aware that the FDA had been held to have authority to regulate tobacco products when it passed the Modernization Act, and explicitly deferred to whatever authority the FDA had as of November 20, 1997.

Whether one interprets this statutory language to mean that Congress affirmatively agrees with the FDA's and the *Coyne* decision that the FDA does have the jurisdiction to regulate cigarettes, or that the passage of the Modernization Act should not be construed to change whatever the scope of the FDA's jurisdiction over tobacco products under the existing statute should be, one thing is clear. Congress did not remove the FDA's jurisdiction over tobacco as it previously had done in the Federal Hazardous Substances Act; Fair Packaging And Labeling Act; Consumer Product Safety Act; and the Toxic Substances Control Act. Moreover, it did not expand on its earlier decision to remove tobacco products under the "dietary supplements" exemption from the definitions of a "drug" in the FDCA itself. Rather, it took no action in that direction whatsoever.

It is respectfully submitted that such legislative language is entirely inconsistent with the Fourth Circuit's view that Congress had such a clear and precise intent on this issue that *Chevron* does not even apply, and that the

agency's interpretation is not entitled to deference. If such a clear and precise intent emerged from the snippets of testimony cited by the Fourth Circuit, surely Congress would have taken this opportunity to reaffirm it – now that the FDA was already regulating cigarettes. At very worst, Congress would have remained silent. But by legislating vaguely and generally that this new modernization statute is not to change the agency's jurisdiction over cigarettes, Congress could not have said more plainly that there exists no clear and precise intent in Congress that the FDA have no jurisdiction whatsoever over cigarettes.

CONCLUSION

Amicus Curiae, Action on Smoking and Health (ASH), respectfully submits that the Fourth Circuit erred in three major ways.

First, instead of applying the deference due agency determinations (including those involving jurisdiction) under *Chevron* whenever Congress has not spoken clearly on the precise issue, the Fourth Circuit utilized long-past Congressional inaction, ignored two recent statutes which addressed the issue, and substituted its own policy judgments regarding how best to deal with a deadly drug to which tens of millions of Americans are already addicted.

Second, instead of recognizing, as the ASH court did, that an agency's interpretation of its jurisdiction which involve issues of fact can be reconsidered from time to time, especially in light of the mountains of newly-discovered but previously-secret evidence of manufacturer intent, the Fourth Circuit relied upon the ASH decision and agency pronouncements pre-dating the discovery of this vital evidence to preclude the FDA from reconsidering this matter in light of new facts.

Third, to the extent that legislative history is even relevant, the Fourth Circuit overlooked two recently passed statutes in which Congress expressly declined to

take (or reaffirm) any position regarding the FDA's jurisdiction over cigarettes, as well as Congress' inaction in seeking to prevent the FDA from proceeding to regulate cigarettes or to even modify the regulations once issued.

ASH respectfully suggests that this Court should not only reverse the Fourth Circuit's decision, but also provide that the FDA's regulations should become effective pending any further proceedings. The public interest in protecting approximately 3000 children a day from first trying cigarettes, and almost half that number from becoming addicted to nicotine, far outweighs the industry's interest in avoiding these regulations. After all, they are far less restrictive than those imposed upon manufacturers of many other drugs which are far less dangerous and not even addictive. Moreover, virtually all of them were agreed to by the cigarette manufacturers themselves as part of a proposed (but failed) national tobacco settlement - a clear indication that they will not impose a major hardship upon the industry.

Respectfully submitted,

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IN THE
Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, *et al.*,
Petitioners,

v.

BROWN AND WILLIAMSON TOBACCO CORP, *et al.*,
Respondents.

On Writ of Certiorari to the
United States Court of Appeals for the Fourth Circuit

**BRIEF AMICUS CURIAE OF PUBLIC CITIZEN, INC.,
AND 33 OTHER PUBLIC HEALTH, CONSUMER, PARENT,
EDUCATOR, AND HEALTH PROFESSIONAL
ORGANIZATIONS IN SUPPORT OF PETITIONERS FOOD
AND DRUG ADMINISTRATION, ET AL.**

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This brief is submitted in support of the Food and Drug Administration ("FDA") rule restricting the sale and promotion of tobacco products to minors. 61 Fed. Reg. 44396 (1996). *Amici* seek reversal of the Fourth Circuit's ruling that the Food, Drug, and Cosmetic Act ("FDCA") does not authorize the FDA to regulate the sale and promotion of tobacco products.¹

INTEREST OF AMICI

Through this brief, 34 *amici* offer the voices of parents, educators, public health advocates, consumers, and physicians and other health professionals. These *amici* have an interest in the reduction of children's access to tobacco products and in shielding children from advertising and promotional efforts aimed at enticing them to use tobacco. *Amici* are more fully described in the attached Appendix.

STATEMENT OF THE CASE

The FDA's petition described the decisions below and the regulatory background. Our statement of the case, therefore, will briefly address only a few important areas of the factual background.

Tobacco use is the single most preventable cause of premature death and disease in the United States. Millions of

¹ In this brief, Petitioners are referred to as the "FDA" or the "Agency." Respondents are referred to collectively as "the industry."

Letters of consent to the filing of this brief have been lodged with the Clerk. Pursuant to Rule 37.6 of this Court, *amici* state that no party had any role in writing this brief and that no one other than *amici* or their counsel made a monetary contribution to its preparation or submission.

Americans are addicted to tobacco products; more than 400,000 people die each year of diseases attributable to tobacco use; nearly one in five eighth graders and one in three twelfth graders smoke cigarettes; and tobacco use that results from addiction to the nicotine in cigarettes causes more Americans' deaths each year than AIDS, alcohol, car accidents, murders, suicides, and fires combined. 60 Fed. Reg. 41314, 41314-15 (1995). Each year, an estimated one million adolescents start smoking, and one-third of those adolescents will die prematurely as a result. 61 Fed. Reg. 44568. Manufacturers carefully engineer their tobacco products to deliver doses of nicotine to consumers, to create and satisfy nicotine addiction. *Id.* 44915-94.

With these facts before it, the FDA determined that the nicotine in tobacco products is "intended to affect the structure or any function of the body," thus bringing it within the FDCA definition of "drugs." 21 U.S.C. § 321(g)(1). That same evidence established that tobacco products are nicotine-delivery systems—a type of "combination product" consisting of drug and device components. 21 U.S.C. § 353(g). Based on these findings, the FDA asserted jurisdiction over tobacco products.

Having concluded that nicotine-containing tobacco products fell within its statutory authority, the FDA promulgated regulations consistent with the public health goals of the FDCA. 61 Fed. Reg. 44398. Two factors were central to the FDA's approach. First, the FDA considered and rejected a ban on tobacco products. *Id.* 44412. The Agency reasoned that determining whether there is a "reasonable assurance" of safety requires consideration of both the risks of using the product and the dangers of withdrawal of the product from the market. *Id.* at 44412-13. Weighing these considerations, the FDA concluded that public health was best served by not banning tobacco products. *Id.*

Second, the FDA concluded that the best way to address the death and disease caused by tobacco products was to eliminate or reduce addiction. And because the overwhelming majority of tobacco users begin to use tobacco products as minors, the FDA determined that the best way to address addiction was to direct its initial regulation at use by young people. *Id.* 44398-99. To effectuate that goal, the FDA issued a number of specific regulations to ensure that tobacco products are not sold or otherwise provided to minors. Among those regulations are requirements that:

- retailers and their employees verify by means of photographic identification that purchasers of tobacco products are 18 years or older (21 C.F.R. § 897.14(b));
- tobacco products be sold in-person, rather than through vending machines or similar devices (§ 897.14(c));
- retailers not open a package of cigarettes or smokeless tobacco to sell a quantity smaller than the quantity in an unopened package (*id.* § 897.14(d)), and that cigarettes not be sold in packages containing fewer than 20 cigarettes (*id.* § 897.16(b)); and
- free samples of cigarettes and smokeless tobacco products not be given to minors (*id.* § 897.16(d)).

In addition, based on evidence that advertising "plays a material role in the decision of children" to use tobacco products, 61 Fed. Reg. 44489, the FDA rule imposes a number of restraints to ensure that the industry's advertising and promotional practices are not directed at minors. These restraints include regulations prohibiting tobacco manufacturers and retailers from:

- using any outdoor advertising, including billboards, within 1,000 feet of any playground or elementary or secondary school (21 C.F.R. § 897.30 (b));

- selling or otherwise distributing promotional items bearing the name, selling message, or logo of a tobacco product (*id.* § 897.34(a)); and
- sponsoring any athletic, musical, artistic or other event that involves a brand name, selling message, logo, or other indicia of product identification (*id.* § 897.34(c)).

The FDA rule represents the first comprehensive federal effort at reducing both the supply of and the demand for tobacco products by our nation's children and adolescents.

In November 1998, 46 state attorneys general and the major domestic tobacco companies reached a settlement of lawsuits brought against the companies by the states. That settlement does not diminish the importance of the FDA rule. The settlement does not grant the states regulatory authority over the manufacture of tobacco products. It does nothing meaningful to warn the public about the health effects of tobacco products, does virtually nothing to restrict the sale of tobacco products to minors, and contains only a fraction of the FDA's restrictions on marketing to children. In addition, the settlement does not require tobacco companies to disclose or alter their products' ingredients and additives, whereas the FDA could promulgate regulations on those topics. Perhaps most importantly, the settlement is an inflexible contract, whereas the FDA's assertion of jurisdiction enables the Agency to continue to revise and refine its regulations based on new science, new studies, or new industry marketing tactics.

The FDCA provides the FDA with broad authority to regulate products that meet the Act's definitions of "drugs" and "devices." With the benefit of research and documents that the industry kept hidden for years, the FDA found that tobacco products fall within those definitions. No one disputes that the

FDA has the power to regulate other nicotine-delivery systems, such as nicotine patches and nicotine gum. No one disputes that the FDA properly intervened when a tobacco company marketed its cigarettes for weight reduction. The only dispute here is whether Congress intended to preclude the FDA from using its authority to protect our children from nicotine addiction and the resulting diseases associated with tobacco use.

SUMMARY OF ARGUMENT

Tobacco is the leading preventable cause of death among Americans, and more than 80 percent of smokers start smoking before they turn 18. Confronted with this public health problem of epidemic proportions, the FDA examined an enormous quantity of material regarding tobacco products. Those documents, which included a wealth of information kept secret by the industry for decades, revealed that tobacco companies had long known more than the public or the government about the health hazards of tobacco products, that the industry purposely marketed its products to children and adolescents, and that it recognized and exploited the addictive nature of nicotine by carefully calibrating nicotine levels in tobacco products.

Based on the evidence it had compiled, the FDA concluded that tobacco products fell within its jurisdiction, as defined under the FDCA. The first step in the Agency's determination was its finding that nicotine in tobacco products is a drug within the meaning of the FDCA because it is "intended to affect the structure or any function of the body." Next, the FDA found that cigarettes and smokeless tobacco products are "pre-filled drug-delivery systems"—combination products consisting of (1) a drug component (nicotine) and (2) device components (filter, ventilation system, processed tobacco) used to deliver the drug to the body. The voluminous

administrative record established that manufacturers knowingly exploit the pharmacological effects of nicotine in tobacco products. Together with the principle that actors are presumed to intend the foreseeable consequences of their conduct, and the fact that the addiction and disease that result from use of tobacco products is well-established, these findings provide a firm basis for the FDA's position. Indeed, many of the industry's own documents confirm that the primary purpose of tobacco products is to deliver nicotine to the body.

In response to the overwhelming body of evidence supportive of the FDA's jurisdictional finding, the industry argues that, even if tobacco products fall within the jurisdictional provisions of the FDCA, those provisions do not provide a basis for the FDA's assertion of authority because Congress has never explicitly said that it intended to allow the FDA to regulate tobacco products. This argument, however, ignores the structure of the Act and the broad authority granted the FDA under it. It also ignores the industry's own conduct in hiding from Congress and the FDA its knowledge about the addictive effect of nicotine and its manipulation of nicotine to exploit that effect. Further, the industry undercuts its own argument by conceding that the FDA may regulate tobacco products marketed with claims of pharmacological effect, such as to help with weight loss. Yet if the industry's theory were correct, the FDA would be precluded from regulating in those instances as well.

Moreover, to the extent that the industry bases its argument on the presence of other statutes that address tobacco products, its plea for repeal by implication falls short. Those other statutes are modest attempts to deal with discrete aspects of the hazards posed by use of tobacco products. The FDA's rule does not conflict with those other statutes, none of which

provides the type of regulation proposed by the FDA or attempts anything near the FDA's comprehensive strategy.

The FDA is the only governmental agency with the authority and expertise to provide comprehensive regulation of the sale, use, and manufacturing of tobacco products. Research shows that the FDA's rule would significantly reduce youth smoking, both by making it more difficult for kids to obtain tobacco products and by eliminating various marketing practices that entice kids to use them. The industry's arguments cannot change the plain language of the FDCA. Combined with the powerful administrative record, that language demonstrates that the FDA's assertion of jurisdiction over tobacco products is well-founded.

ARGUMENT

I. THE FDCA AUTHORIZES THE FDA TO REGULATE TOBACCO PRODUCTS.

In 1972, an R.J. Reynolds researcher wrote, "In a sense, the tobacco industry may be thought of as being a specialized, highly ritualized and stylized segment of the pharmaceutical industry." 61 Fed. Reg. 44867. That same year, a Philip Morris scientist wrote, "Think of the cigarette as a dispenser for a dose unit of nicotine." *Id.* 44856. In 1981, Brown & Williamson's parent corporation, BATCO, wrote, "In a nutshell, our approach has been to regard nicotine as a drug." *Id.* 44888.

Notwithstanding this record, the industry argues that tobacco products are neither "drugs" nor "drug-delivery devices" under the FDCA. This argument is based on the mistaken claim that only a company's *public* representations about a product's *therapeutic* effects can bring the product

within the statutory definitions of drugs or devices. According to the industry, as long as manufacturers are careful about what they say, the FDA cannot act, no matter how addictive a product or how much evidence the Agency possesses about manufacturers' intent. As the district court recognized, however (Pet. App. 109a, 115a), and the majority below never disputed, the FDCA definitions of drugs and devices are not nearly so narrow.

Applying the FDCA definitions, the nicotine in tobacco products is a drug because it is intended to have a pharmacological effect, and cigarettes and smokeless tobacco products are devices used to deliver the drug nicotine to the body. Together, the drug and the device form a "drug-delivery system," a type of "combination product" that (1) contains a drug, as that term is defined by the FDCA, and (2) has the primary purpose of delivering or aiding in the delivery of the drug. The FDA may appropriately regulate such products under either its drug or device authorities.

A. Nicotine In Tobacco Products Is A
"Drug" As Defined In The FDCA.

The FDCA defines the term "drugs" as, among other things, "(B) articles intended for the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1). Thus, a product that has pharmacological effects on the body—bringing it within the lay understanding of "drug"—falls within the statutory definition if it is intended *either* (1) to be used to treat or prevent disease *or* (2) to otherwise affect the body. *See also United States v. An Article of Drug ... Bacto-Unidisk*, 394 U.S. 784, 793 (1969) (FDCA

definition of "drug" is term of art that encompasses far more than strict medical definition).

The fact that nicotine has pharmacological effects on the human body is undisputed. Indeed, the FDA regulates other nicotine products, such as nicotine patches and nicotine chewing gum; and the tobacco industry has not challenged the FDA's assertion of jurisdiction over those products. In this case, the FDA's authority is based on its determination that nicotine in tobacco products is a drug within the meaning of subsection (C) because it is "intended to affect the structure or any function of the body." 61 Fed. Reg. 44403.

1. The FDA based its finding of "intent" on evidence of foreseeability, consumer use, and internal industry documents. The FDCA does not define "intend." Thus, the Court should construe the term according to "its ordinary meaning." *Asgrow Seed Co. v. Winerboer*, 513 U.S. 179, 187 (1995). The dictionary cited by the district court defined "intend" as "[t]o have in mind; plan . . . [t]o design for a specific purpose. . . . [t]o have in mind for a particular use." Pet. App. 105a (quoting *The American Heritage Dictionary* 668 (2d ed. 1991)). As the district court further noted, the legal usage of the word "includes the principle that one intends the readily foreseeable consequences of his actions." Pet. App. 105a (citing *Agnew v. United States*, 165 U.S. 36, 53 (1897)). Given these definitions, nothing in the plain meaning of the FDCA indicates that Congress intended to limit the FDA to evidence based on manufacturers' marketing claims.²

² As the district court found, the legislative history of the FDCA and court decisions construing the Act support this conclusion. *See* Pet. (continued...)

The FDA's regulations regarding the meaning of "intended uses" also support the Agency's assertion of jurisdiction here. Those regulations state that "'intended uses' or words of similar import" refer to the "objective intent of the persons legally responsible for the labeling of drugs." 21 C.F.R. § 201.128; *see id.* § 801.4 (devices).

The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, . . . be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. . . .

Id. § 201.128 (drugs); *id.* § 801.4 (devices). This definition plainly allows the Agency to rely on evidence other than manufacturer representations to establish intended use.³

Foreseeability: Nicotine affects the structure or function of the body. "Nicotine's effects on the brain are the biological basis of nicotine addiction—an addiction that has been proven by a wealth of laboratory and epidemiological evidence and

²(...continued)
App. 107-08.

³ The industry claimed below that the FDA's interpretation of the term "intent" in connection with the regulations was "unprecedented." In fact, the regulations defining intent, 21 C.F.R. §§ 201.128, 801.4, were issued in the 1950s and are in keeping with centuries of Anglo-American law. *See Hadley v. Baxendale*, 156 Eng. Rep. 145 (1854).

recognized by every major independent medical organization that has studied the question." 61 Fed. Reg. 44701; *id.* 44702-06. Of course, having conducted numerous studies on nicotine's pharmacological effects, the industry knows this fact. Even if the manufacturers feigned ignorance, however, they have no legal right to disregard facts that have become common knowledge.

Applying an "objective" standard for "intent," the manufacturers are charged as a matter of law with having foreseen the reasonable consequences of their actions. *See Lee v. Lee County Bd. of Educ.*, 639 F.2d 1243, 1267 (5th Cir. 1981) (objective intent "presumes that a person intends the natural and foreseeable consequences of his voluntary actions"). And the reasonable consequence of the manufacturers' actions—marketing products containing a pharmacologically active dose of nicotine—was and is to affect the structure and function of the bodies of users of tobacco products. Because the effect is so great—as many as 92 percent of smokers are addicted to nicotine, 61 Fed. Reg. 44730—any claim that such consequences are not foreseeable is not credible.

Consumer use: Evidence of actual consumer use is also germane to intent. *See* H.R. Rep. No. 94-853 at 14 (1976) (FDA may consider "actual use of a product in determining whether or not it is a device."); Pet App. 111a-112a (district court opinion) (citing cases in which courts have recognized that intended use may be determined by looking to actual use). Here, consumer use confirms that the manufacturers' purposeful manipulation of the form and content of nicotine in their products is intended to create and satisfy consumer addiction. Manufacturers' own documents reaffirm that the industry "foresees" the connection between its manipulation of nicotine delivery and the public's use of tobacco products for

pharmacological effects. 61 Fed. Reg. 44854-5097. Data regarding consumer use establish that the foreseeable results in fact come to pass. *Id.* 44807-46.

Industry documents: Industry documents show that tobacco manufacturers are keenly aware that consumers buy tobacco products mainly to satisfy addiction. See 21 C.F.R. § 201.128. For example, a Philip Morris report cited nicotine as "the primary reason" why people smoke and placed tobacco products in the category of "nicotine delivery devices," along with nicotine patches and nicotine gum. 61 Fed. Reg. 44854, 44866. An R.J. Reynolds memorandum, referring to "the confirmed user of tobacco products," acknowledged that "[h]is choice of product and pattern of usage are primarily determined by his individual nicotine dosage requirements. . . ." *Id.* 44868. And Brown & Williamson and its parent BATCO have referred to nicotine as the reason "why people inhale smoke." *Id.* 44880. These and numerous similar statements found in company documents are not stray comments of low-level employees. Rather, they are admissions rightly imputed to the companies and accepted by the FDA to show that the industry intends its products to have pharmacological effects.

In addition to establishing the industry's knowledge that its products are used as nicotine-delivery devices, documents before the FDA reveal that manufacturers research and design their products specifically for this purpose. The documents show that tobacco companies, through their manufacturing processes, can and do control the amount, form, and delivery of nicotine in their products, all in a deliberate effort to exploit the pharmacological effects. *Id.* 44917-46 (cigarettes); *id.* 45108-24 (smokeless tobacco companies use product-design features to control nicotine delivery and to promote tolerance and addiction to nicotine); *e.g.*, *id.* 44942 (addition of ammonia to

increase delivery of nicotine); *id.* 44868 (memo from cigarette manufacturer referring to cigarette as "nicotine delivery system"). Such documents offer unambiguous evidence that tobacco products are "design[ed] for a specific purpose" and that manufacturers have their products "in mind for a particular use"—that is, to deliver nicotine to the body. See Pet. App. 105a (district court) (quoting definition of "intent" in *The American Heritage Dictionary*).

Thus, the administrative record demonstrates not only that manufacturers of tobacco product reasonably foresee that their products will be used for the pharmacological effects of nicotine, and that their products are actually used for this purpose, but also that they engineer their products to exploit and promote those effects, in particular the effect of addiction. The voluminous record establishes that manufacturers consider their products nicotine-delivery systems and that they have done extensive studies of the effects of nicotine, including addictiveness, to enable them to better design their products to maintain addiction.

Manufacturer claims: The industry has further argued that the intent component of the subsection (C) definition of drugs, *see supra* p. 8, can be satisfied *only* by industry statements making express health claims (for example, weight loss, stress reduction, appetite suppression). Because manufacturers make no therapeutic claims for their products, the industry contends, the FDA cannot regulate them.

Neither the statutory language nor the legislative history requires therapeutic uses or specific therapeutic claims for a product to qualify as a drug or device. Rather, under subsection (C), the FDA may regulate products marketed without such representations as long as the products are *intended* to be used

for their pharmacological effects. See *United States v. 789 Cases, More or Less, of Latex Surgeons' Gloves*, 799 F. Supp. 1275, 1285 (D.P.R. 1992) ("All of the circumstances surrounding the promotion and sale of the product constitute the 'intent.' It is not enough for the manufacturer to merely say that he or she did not 'intend' to sell a particular product as a device."). Thus, for example, in 1987, the FDA determined that Advanced Tobacco Products' new product FAVOR, a cigarette-like device consisting of a plug impregnated with a nicotine solution inserted with a tube, corresponding in appearance to a conventional cigarette, was a new drug intended as an alternative nicotine-delivery system for cigarette smokers, to satisfy nicotine dependence and to create nicotine effects.⁴

As support for the argument that "intent" can be manifested only by public claims of therapeutic effect, the industry has relied on FDA statements made at congressional hearings and on the FDA's denial of a 1977 petition to the FDA filed by Action on Smoking and Health ("ASH"), which urged the FDA to assert jurisdiction over cigarettes sold without therapeutic claims. The industry's reliance on the Agency's past statements is misplaced.

First, the FDA's response to the ASH petition explicitly recognized that the determination of intent was not dependent on manufacturers' public claims and that objective evidence, including evidence of consumer use, could outweigh the manufacturers' statements. Letter from FDA Commissioner to John Banzhaf, Nov. 25, 1980, at 8-9 (citing *National Nutritional Foods Ass'n v. FDA*, 504 F.2d 761, 789 (2d Cir.

⁴ The "combination product" provision of the FDCA was not enacted until 1990.

1974)) (Exh. 2 to Plaintiffs' Second Brief in Support of Summary Judgment). The FDA found, however, that the ASH petition lacked sufficient evidence on this point. *Id.* Accordingly, until the FDA obtained additional evidence (for example, that as many as 92 percent of smokers are addicted and that manufacturers deliberately control the level and form of nicotine in their products to addict users, to keep users hooked, and to provide the physical effects of nicotine), the Agency's consideration of intent was controlled by the industry's promotional statements. The tobacco industry's avoidance of express health claims and its lies to Congress and the public about its knowledge of nicotine's addictiveness left the FDA in 1977 with no recourse but to disclaim jurisdiction over tobacco products. Even if the FDA agreed with the ASH assertions in 1977, it lacked the *evidence* on which its 1996 final rule is based. Only now does the FDA have proof of manufacturers' extensive research into the pharmacological effects of nicotine and their manipulation of the amount and delivery of nicotine entitles the Agency to regulate tobacco products as drugs. See generally 61 Fed. Reg. 44915-49; see also *Action on Smoking and Health v. Harris*, 655 F.2d 236, 239 (D.C. Cir. 1980) ("Nothing in this opinion should suggest that the [FDA] is irrevocably bound by any long-standing interpretation and representations thereof to the legislative branch" regarding its jurisdiction over tobacco products).

Second, the prior FDA statements on which the industry relies do not bear on whether the FDCA grants the FDA authority over tobacco products. Even if the Agency had previously interpreted the FDCA to assess intent solely by whether a manufacturer made express therapeutic claims, the Agency would be free to reject a prior interpretation of its organic statute. *Rust v. Sullivan*, 500 U.S. 173, 186 (1991) (even where agency's interpretation of statute represents "break

with prior interpretations," courts will grant it substantial deference) (citing *Chevron, U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 862 (1984)); *id.* at 184. An agency must "provide a reasoned explanation for its" change in position, *Action on Smoking and Health*, 655 F.2d at 242 n.10, but it is not required to "establish rules of conduct to last forever." *Motor Vehicles Mfrs. Ass'n v. State Farm Mutual Ins. Co.*, 463 U.S. 29, 42 (1983). See *United States v. Southwestern Cable Co.*, 392 U.S. 157 (1968). And if the statutory language is ambiguous, an agency's regulations will be upheld as long as they are "based on a permissible construction of the statute." *Chevron*, 467 U.S. at 842-43.

Here, the FDA's present interpretation is the most straightforward because nothing in the statutory language defining "drug" or the regulatory language defining "intent" limits determinations of intent to public statements. If it did, Prozac could be sold as an unregulated product as long as it was advertised without health claims, although its manufacturer knew it would have pharmacological effects and controlled its contents to produce those effects.

The FDA's interpretation also serves the important policy goal of preventing drug manufacturers from side-stepping the regulatory process by misrepresenting their true objectives or by carefully phrasing public statements in the face of known pharmacological effects produced by ordinary use of the product. At the same time, the FDA's interpretation protects against FDA regulation of products, for example, model airplane glue, that can be used to affect the structure or function of the body but are neither engineered, sold, nor used by most consumers for that purpose. Accordingly, the FDA's action is based on "a plausible construction of the plain language of the

statute and does not otherwise conflict with Congress' expressed intent." *Rust v. Sullivan*, 500 U.S. at 184.

B. Cigarettes And Smokeless Tobacco Products Are Nicotine-Delivery Systems.

The FDA properly decided to regulate tobacco products as drug-delivery systems. Because nicotine is a drug within the meaning of the FDCA, and because tobacco products are intended to deliver that drug to the user, cigarettes and smokeless tobacco products precisely fit the definition of "combination products," 21 U.S.C. § 353(g). The designation and treatment of combination products is not an *ad hoc* artifice created by the FDA for the purpose of regulating tobacco. Rather, the FDA's action is based on the FDCA and an agreement between the FDA's Center for Drug Evaluation and Research ("CDER") and its Center for Devices and Radiological Health ("CDRH"), entered into in October 1991, well before tobacco was on the FDA's agenda. Pursuant to that agreement, the FDA treats products that are distributed containing a drug and that have the primary purpose of delivering or aiding in the delivery of the drug (a "pre-filled drug-delivery system," such as a pre-filled syringe) as combination products, which may be regulated under either the drug or the device regulations. 61 Fed. Reg. 44402-03.

Cigarettes deliver the drug nicotine to the body through inhalation into the lungs, much like other combination products, such as nebulizers. In addition, certain cigarettes have been specifically marketed for drug delivery. For example, in the 1970s, Asthmador cigarettes were sold as an asthma treatment in the United States. As recently as a few years ago, in France, Cigarettes Schulze Bengalias used the cigarette form to treat respiratory systems disorders by delivering to the body drugs

such as those in stramonium leaf and digitalis leaf. *See also United States v. 354 Bulk Cartons*, 178 F. Supp. 847 (D.N.J. 1959) (cigarette marketed for weight reduction); *United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes*, 113 F. Supp. 336 (D.N.J. 1953) (cigarette marketed to prevent respiratory and other disease).

Smokeless tobacco products deliver nicotine to the body through absorption into the buccal pouch, the inner lining of the cheek. This means of delivery is particularly effective because it allows the drug to enter the bloodstream directly from the buccal pouch, in contrast to the slower passage of a pill through the stomach. Other products that deliver drugs to the body through the membranes lining the mouth, without being swallowed, include various nitrates used to treat chest pain, such as angina; Fentanyl Oralet, a lollipop that delivers an anesthetic by initial rapid absorption through the mouth, as well as by slower delivery through the gastrointestinal tract; asper-gum, and nicotine gum.

The industry argued below that the FDA may not regulate tobacco products under the device regulations because the products achieve their effect through "chemical action," and the definition of devices excludes items that "achieve [their] primary intended purposes through chemical action." *See* 21 U.S.C. § 321(h). Under the FDCA, however, combination products necessarily have both drug components, which affect the body through chemical action, and device components, which do not. 21 U.S.C. § 353(g). Frequently, the device components of the combination product do not in themselves have an effect on the structure or function of the body. A syringe, for example, does not affect the body; only the drug injected through that device does so.

Moreover, although the statute specifies that for combination products that act primarily as drugs (such as tobacco products), "the persons charged with premarket review of drugs shall have primary jurisdiction," the FDCA says nothing about which regulations the FDA must apply to those products. 21 U.S.C. § 353(g). That issue is addressed only by the agreement between CDER and CDRH, *supra* p. 17, which allows the FDA to regulate a pre-filled drug-delivery system under either the drug or the device regulations, no matter what the product's primary mode of action. 61 Fed. Reg. 44400-01. Although the industry seeks to force the FDA to regulate such products as drugs, it has offered no cogent reason for imposing such a requirement on the FDA. Neither the statute, its legislative history, the regulations, nor FDA precedent requires such a restriction. Thus, the district court properly deferred to the FDA's decision to regulate tobacco products as devices.

The industry further contended below that tobacco products are not combination products because the device components could not be regulated apart from the drug nicotine. That argument seeks to impose a requirement beyond that established by the clear language of the statute, 21 U.S.C. § 353(g), which plainly permits the FDA to regulate products like nebulizers and transdermal patches as combination products. (In fact, the industry has conceded that nicotine patches are regulable as combination products. *See* Industry D. Ct. "Second Brief" at 28, 29.) Nebulizers and transdermal patches, without their drug components, are basically canisters and stickers. Like cigarettes or chewing tobacco, those canisters and stickers are intended to deliver a drug to the product's user. Thus, for regulatory purposes under the FDCA, each is a drug-delivery system. *See also* 61 Fed. Reg. 44866 (Philip Morris report places cigarettes and smokeless tobacco in same category of "nicotine delivery devices" as nicotine patches and gum). And,

like used cigarettes and used smokeless tobacco products, when the drug has been extracted from the canisters or stickers, the devices are worthless.

C. The Fourth Circuit's Approach Is Contrary To The Structure Of The FDCA.

Although the definition provisions of the FDCA establish the scope of the FDA's jurisdiction, the Fourth Circuit found that the FDA had no jurisdiction over tobacco products based on a lack of specific indicia that Congress intended to give the Agency such authority. By framing the jurisdictional question in that way, the court below transformed the relevant question from whether Congress *withheld* authority over tobacco products from the FDA to whether Congress *delegated* such authority to the FDA. Pet. App. 15a.

The Fourth Circuit's approach is contrary to the structure of the FDCA. The FDCA's definitions do not name any specific products. The statute works as a general grant of authority over the categories of products set forth in the definition provisions. Thus, if a product fits the definition of "drugs" or "devices" and is not expressly excluded from the scope of the definition, the FDA is empowered to assert jurisdiction.

In essence, the Fourth Circuit was concerned that the FDA was trying to fit a square peg into a round hole. Purporting to discern congressional intent by considering the jurisdictional provisions in the context of the statute as a whole, the court claimed to have found that regulation of tobacco products did not fit comfortably into other specific FDCA provisions. In this regard, the court erred for several reasons.

First, the applicability of the definition provisions is apparent on their face. *See supra* at I.A. Indeed, the Fourth Circuit's opinion suggests that the FDA's reading of the definition provisions is entirely plausible. Pet. App. 19a. Yet not only did the court give the Agency no deference as to the scope of those provisions, the court rushed past those provisions with minimal discussion and no analysis. *Id.*

Second, although consideration of other provisions often aids statutory interpretation, the court below nonetheless erred in giving other provisions more weight than the jurisdictional provisions actually at issue. That is, the Fourth Circuit's approach robbed the definition provisions of their function—to outline the scope of FDA jurisdiction—on the theory that those definitions do not apply to a product unless regulation of that product fits as neatly into all of the other provisions as it does into those jurisdictional provisions. In this way, the Fourth Circuit improperly substituted its judgment on how to regulate tobacco products for the judgment of the expert agency charged by Congress with implementing the statute. The answer to the question of how to regulate, however, is one uniquely within the Agency's expertise. Accordingly, as to that question, the Agency's view deserves deference if it reflects a plausible construction of the statute. *Rust v. Sullivan*, 500 U.S. at 184; *Chevron*, 467 U.S. at 843. Thus, even if the FDA's regulatory scheme were imperfect, as the Fourth Circuit thought, that imperfection would not constitute grounds for stripping the FDA of statutory authority founded on the FDCA's jurisdictional provisions.

Furthermore, the Fourth Circuit's approach suggests that the FDA must decide all issues about how to regulate a product at the point at which it first asserts jurisdiction and that the assertion of jurisdiction requires the Agency to apply all relevant

statutory provisions in a timely manner. Thus, for example, the Fourth Circuit said that the FDA's failure yet to classify tobacco products as class I, II, or III devices is evidence that tobacco products do not fall within the Agency's jurisdiction because the FDCA requires the FDA to classify all medical devices. Pet. App. 27a. The Fourth Circuit's approach, however, does not reflect the way in which FDA regulates medical devices. In practice, the FDA often delays regulatory action with respect to specific products. See, e.g., *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 n.3 & 479 (1996) (noting slow pace of FDA's initiation of premarket approval process for devices already on market). For example, the FDA did not classify numerous medical devices until years after enactment of the medical device laws in 1976. See, e.g., 21 C.F.R. §§870.3600, 870.3610, 870.3620, 870.3680, 870.3700 (numerous pacemaker components classified in 1980); *id.* § 876.3350 (penile implants classified in 1983); *id.* § 870.3375 (cardiovascular intravascular filters classified in 1980); *id.* § 868.5610 (membrane lungs for long-term pulmonary support classified in 1982). Thus, the FDA's failure to classify tobacco products in 1996 is not an indication that the Agency cannot regulate in accordance with the statute. Rather, it reflects the usual pace of Agency action in this area.

The Fourth Circuit took its argument about classification one step further by suggesting that the FDA did not classify tobacco products because all three device categories require that the products within that category have a reasonable assurance of safety and effectiveness. Because the FDA does not believe that tobacco products are safe, the Fourth Circuit continued, classifying tobacco product would require the Agency to ban them. Pet. App. 27a-28a. First, the FDA disagrees that asserting jurisdiction requires it to ban tobacco products. See

supra p. 3.⁵ Second, the lower court's argument does not constitute a reason to find that the FDCA does not confer authority on the Agency where such authority is found in the jurisdictional provisions of the statute. Speculation about what the Agency could, would, or should do if it has jurisdiction is a separate question from whether the Agency has jurisdiction at all. And at this stage of the proceedings, the question of how the Agency should regulate—as opposed to whether it can regulate at all—is not even before the Court.

* * * * *

In crafting the broad definitions that form the basis of the FDA's authority, Congress left to the FDA's expertise decisions about which specific products are covered by the Act. Exercising its expertise, the FDA regulates numerous products that fall within the FDCA's definitions but might not comport with a lay understanding of a drug or a medical device. See, e.g., 21 C.F.R. § 878.4635 (tanning booth), § 880.6050 (ice bag), § 880.6265 (examination gown), § 886.5842 (eyeglass frames), § 886.5850 (non-prescription sunglasses). Nonetheless, unless expressly excluded from the FDCA's definitions of drugs or devices, any product that meets one of those definitions falls within the FDA's jurisdiction. Nicotine in tobacco products meets the FDCA definition of a drug. Therefore, the Court should uphold the district court's ruling

⁵ The FDA has stated that it has no intention of banning tobacco products. 61 Fed. Reg. 44419. In reaching this decision, the FDA looked to the public health impact and the economic impact of banning tobacco products and concluded that the public health would best be served by taking steps to reduce the number of children who start smoking. *Id.* 44412-13.

that nicotine-containing tobacco products are subject to the FDA's regulatory authority.

II. CONGRESS HAS NOT PRECLUDED THE FDA FROM REGULATING TOBACCO PRODUCTS.

Because tobacco products fit the FDCA definition of combination drug-device products, the FDA has jurisdiction to regulate them unless Congress has otherwise withheld jurisdiction. Attempting to uncover such congressional intent, the industry has pointed to statutes specifically authorizing other agencies to regulate some aspect of the tobacco business and to the fact that Congress has not enacted laws that explicitly tell the FDA to regulate tobacco. Yet Congress nowhere indicated that the statutes on which the industry relies were intended to affect the scope of the FDA's jurisdiction under the FDCA. And the argument that this case can be decided by divining the meaning of congressional silence is without merit.

1. Under our Constitution, Congress may make laws that affect the conduct of others only in one manner: "by a bill that passes both Houses and is either signed by the President or repassed by a supremajority after his veto." *United States v. Estate of Romani*, 118 S. Ct. 1478, 1488-89 (1998) (Scalia, J., concurring) (citing U.S. Const., Art. I, § 7). There is no other means by which Congress may constitutionally act. *INS v. Chadha*, 462 U.S. 919, 951 (1983) ("[T]he legislative power of the Federal Government [must] be exercised in accord with a single, finely wrought and exhaustively considered, procedure"). *Accord Central Bank v. First Interstate Bank*, 511 U.S. 164, 186 (1994). Since, as *Chadha* held, Congress may not, even in a statute, delegate the power to make law in any other way, congressional inaction here cannot deny to the FDA the power to regulate tobacco products if the FDA otherwise has such

power. *Cf. Train v. City of New York*, 420 U.S. 35, 45 (1975) ("Legislative intention, without more, is not legislation.").

The industry has never claimed that any express provision precludes the FDA from regulating tobacco products as drug-delivery systems because no such provision exists. This absence is striking because when Congress wants to preclude an agency from exercising authority over tobacco products, it does so explicitly. For example, as part of the Dietary Supplement Amendments of 1994, Congress defined "dietary supplement" to exclude "tobacco" products. 21 U.S.C. § 321(ff). That definition is in the same statute, the FDCA, as the definitions of drug and device on which the FDA relies. *See* 21 U.S.C. §§ 321(g)(1) & (h). Thus, Congress could have precluded FDA jurisdiction here had it intended to do so. Also in Title 21, Congress defined "controlled substance" by expressly excluding "tobacco." 21 U.S.C. § 802(6). And elsewhere, Congress expressly prohibited other agencies from regulating tobacco products under other broad regulatory regimes: "chemical substance" under the Toxic Substances Control Act excludes "tobacco or any tobacco product," 15 U.S.C. § 2602 (2)(B)(iii); "hazardous substance" under the Federal Hazardous Substances Act, 15 U.S.C. § 1261(f)(2), excludes "tobacco or tobacco products." Similar exclusions are also contained in the Consumer Product Safety Act (15 U.S.C. § 2052(a)(1)(B)) and the Fair Packaging and Labeling Act (15 U.S.C. § 1459(a)(1)). Congress has not enacted such an exclusion here, and the Court should not do so in its stead.

The industry admits that the FDA has jurisdiction over *some* tobacco products—those sold with claims of health benefits. *See Fairfax Cigarettes*, 113 F. Supp. 336; *354 Bulk Cartons*, 178 F. Supp. 847. Attempting to make its position seem consistent, the industry suggests that Congress "approved"

those cases in the same way that it allegedly disapproved the FDA's assertion of jurisdiction here—by doing nothing. To distinguish cases in which FDA jurisdiction is appropriate from cases in which it is not, the industry says that Congress has "withheld" FDA authority only over tobacco products "as customarily marketed." That phrase, however, appears nowhere in the statute or its history, although Congress has written that type of restriction into other statutes. See 15 U.S.C. § 1459(a) ("consumer commodity" is product "customarily produced or distributed for sale through retail sales agencies"). Yet if Congress actually forbade the FDA from regulating tobacco products, such a ban would include cases where health claims are asserted because nothing in the FDCA makes the FDA's jurisdiction over tobacco products turn on how the products are "customarily marketed." Even the industry concedes that such a result would not square with the FDCA.

2. In a related argument, the industry has asserted that Congress has comprehensively regulated tobacco products in a way that leaves no room for the FDA. The Fourth Circuit restated this theory as an argument that tobacco-specific statutes show that Congress did not intend to allow the FDA to regulate tobacco products under the general authority provided it in the FDCA. As the district court found, however, the statutes at issue do not support the arguments built upon them.

FCLAA: The industry has argued that the Federal Cigarette Labeling and Advertising Act of 1965, as amended, ("FCLAA") regulates tobacco products so comprehensively that it preempts the entire field of tobacco regulation. The FCLAA's federal preemption provision, 15 U.S.C. § 1334(a), restricts federal agencies only from mandating additional statements relating to smoking and health "on any cigarette package," which the FDA's rules do not do. Furthermore, prior to the

1969 amendments to the statute, when a broader preemption provision applied to federal agencies, the D.C. Circuit in *Banzhaf v. FCC*, 405 F.2d 1082, 1088, 1090 (1968), narrowly construed the preemption provision to cover only requirements for affirmative statements related to smoking and health.

Although the declaration of policy contained in section 1 of the original 1965 FCLAA stated that Congress intended to enact a "comprehensive" program regarding the labeling and advertising of cigarettes, the statute plainly is not a comprehensive cigarette regulatory law. Rather, the statute precludes federal agencies from acting only to the extent stated in 15 U.S.C. § 1334(a). Surely, the industry does not contend that state laws banning cigarette sales to minors are somehow preempted by the FCLAA. And no one could seriously suggest that a public school's ban on cigarette advertisements in the school newspaper or a prohibition on distributing free samples on school grounds would be preempted. In fact, the Fourth Court has rejected a preemption challenge to a Baltimore ordinance that contains an even broader ban on billboard tobacco advertising than the FDA rule. *Penn Advertising v. Mayor & City Council of Baltimore*, 101 F.3d 332 (4th Cir. 1996), *cert. denied*, 117 S. Ct. 1569 (1997). Since the FCLAA does not even preempt all regulation of cigarette advertising, it certainly does not preempt the entire field of tobacco regulation.

Smokeless Tobacco Act: For similar reasons, the Comprehensive Smokeless Tobacco Health Education Act, 15 U.S.C. § 4406(a), does not preempt the field of smokeless tobacco regulation. The preemption provision in that Act bans federal and state laws requiring additional statements on packages and in advertisements beyond those mandated by Congress (but excludes billboards from its reach). It does not preempt any other federal, state, or local regulation.

ADAMHA: The industry has also claimed that the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992, 42 U.S.C. § 300x-26 ("ADAMHA"), eliminates all FDA jurisdiction over tobacco. In fact, the ADAMHA is a modest effort to reduce underage tobacco use by strengthening state efforts to enforce laws restricting youth access. The ADAMHA does not impose mandatory requirements, as any state may choose to forego federal funding for substance abuse programs rather than to increase enforcement. The statute imposes no federal sanctions for sales to minors. It contains no provisions designed to reduce minors' demand for tobacco products. And, most significantly, it has no preemption provision of any kind. About all that can meaningfully be said about the ADAMHA in the context of this case is that it confirms the FDA's view that underage tobacco use is a serious problem and shows that Congress was willing to use federal tax dollars to enlist the states in the fight.

Moreover, the broad preemption by implication theory espoused by the industry here was rebuffed by the Court in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), and more recently in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). Indeed, accepting the logical reach of the ADAMHA argument would result in revocation of the FDA's long-standing jurisdiction over tobacco products for which health claims are made. The Court should reject this attempt to transform a narrow law designed to protect minors into a law that shields the tobacco industry.

3. Because no statute actually forbids the FDA from regulating tobacco, the industry has tried to convert congressional failures to enact positive authorizing legislation into a basis for denying the FDA the power to regulate tobacco products. However, "[c]ongressional inaction cannot amend a

duly enacted statute." *Patterson v. McLean Credit Union*, 491 U.S. 164, 175 n.1 (1989). As Justice Scalia has admonished:

[O]ne must ignore rudimentary principles of political science to draw any conclusions regarding [congressional] intent from the failure to enact legislation. The "complicated check on legislation," *The Federalist* No. 62, p. 378 (C. Rossiter ed. 1961), erected by our Constitution creates an inertia that makes it impossible to assert with any degree of assurance that congressional failure to act represents (1) approval of the status quo, as opposed to (2) inability to agree upon how to alter the status quo, (3) unawareness of the status quo, (4) indifference to the status quo, or even (5) political cowardice.

Johnson v. Transportation Agency, 480 U.S. 616, 671-72 (1987) (Scalia, J., joined by Rehnquist, C.J., dissenting). See *Estate of Romani*, 118 S. Ct. at 1488-89 (Scalia, J., concurring).

An example forcefully illustrates why it is inappropriate to rely on congressional inaction to establish the meaning of duly enacted laws. After the FDA published its proposed rule, several Members of Congress from North Carolina and Kentucky introduced bills that would have explicitly forbidden the FDA from regulating tobacco products. See 61 Fed. Reg. 45259 (citing bills). Those bills were not enacted. Under the industry's theory, such inaction would constitute a decision by Congress to allow the FDA to proceed. Or suppose that such a bill were passed by both Houses, but that the President vetoed it, and an override vote fell one vote short in one House. Under the industry's approach, a court should construe that outcome

as acquiescence in the FDA's authority over tobacco products. Indeed, the industry's approach to congressional inaction would mean that Congress implicitly ratified the FDA's final rule, by failing to overrule the rule pursuant to the 1996 amendments to the Administrative Procedure Act, under which the effective date of all major rules is delayed to allow Congress time to enact a joint resolution of disapproval. 5 U.S.C. §§ 800 *et seq.*

All of these attempts to use legislative silence are inappropriate. The only way to interpret what Congress meant in a statute is by examining that statute, with all of the proper tools of legislative interpretation. As discussed above, such examination demonstrates that the FDCA authorizes the FDA to regulate tobacco products.

CONCLUSION

For the foregoing reasons, the decision of the Fourth Circuit should be reversed.

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Respectfully submitted,

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APPENDIX

The foregoing brief is submitted on behalf of the following ~~46~~ ³³ *amici*:

PUBLIC CITIZEN, INC. is a consumer advocacy organization founded by Ralph Nader in 1971 and has approximately 150,000 members nationwide. Public Citizen's members are ordinary consumers who are concerned that their children and grandchildren will be enticed into experimenting with tobacco products by the promotional efforts of the tobacco industry and that they may become addicted to tobacco products as a result. Public Citizen has substantial experience working on tobacco-related issues before courts, regulatory agencies, and Congress. In addition, Public Citizen has long been active before Congress, regulatory agencies, and the courts in matters relating to public health in general and drug and medical device regulation in particular. Public Citizen submitted comments to the Food and Drug Administration on the agency's proposed tobacco regulations.

ALLIANCE FOR LUNG CANCER ADVOCACY, SUPPORT, AND EDUCATION (ALCASE) is a nonprofit organization dedicated to helping people, worldwide, at risk for and living with lung cancer improve the quality of their lives. ALCASE advocates for increased awareness about issues surrounding prevention, early diagnosis, treatment, and living with lung cancer; provides psychosocial support, which is known to have a positive effect on the quality of life for most people with lung cancer; and provides education about the disease and how best to live with it.

AMERICAN ACADEMY OF FAMILY PHYSICIANS (AAFP) is a not-for-profit professional association that represents family physicians. The AAFP has 88,000 members and is comprised of practicing physicians, residents, and medical students. The

Academy has a longstanding interest in tobacco control at the federal and state level. Comprehensive legislation has been one of the most important public health priorities of the AAFP for many years.

AMERICAN ACADEMY OF PEDIATRICS is a non-profit corporation with 66 chapters in the United States, its territories, and Canada. The Academy is an organization of 55,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists, dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults. The Academy engages in advocacy, research, and public education, among other things, on issues related to tobacco and the health of minors. The Academy submitted comments to the FDA on the agency's proposed tobacco regulations.

AMERICAN ASSOCIATION FOR RESPIRATORY CARE (AARC), a national society of health care professionals, is sponsored by the American College of Chest Physicians, the American Society of Anesthesiologists, and the American Thoracic Society. AARC is dedicated to maintaining the highest standards of practice in respiratory care. Respiratory care is defined as a health care specialty under medical direction in the assessment, treatment, management, control, diagnostic evaluation, and care of patients with deficiencies and abnormalities of the cardiopulmonary system.

AMERICAN ASSOCIATION OF CRITICAL-CARE NURSES is the world's largest specialty nursing organization with more than 68,000 members. Founded in 1969, the Association has more than 270 chapters worldwide and is working toward a health-care system driven by patient's needs where critical care professionals make their optimal contribution.

AMERICAN ASSOCIATION OF UNIVERSITY WOMEN (AAUW), an organization of 150,000 members, has been a catalyst for the advancement of women and their transformations of American society for more than a century. In more than 1,500 communities across the country, AAUW members work to promote education and equity for women and girls. AAUW plays a major role in activating advocates nationwide on AAUW's priority issues. Current priorities include gender equity in education, reproductive choice, and workplace and civil rights issues. AAUW recognizes the need to combat the long-term health consequences of early tobacco addiction, particularly in women and girls.

AMERICAN COLLEGE OF CARDIOLOGY, a 24,000 member professional medical society, was chartered and incorporated as a teaching institution on December 2, 1949. The mission of the American College of Cardiology is to foster optimal cardiovascular care and disease prevention through professional education, promotion of research, leadership in the development of standards and guidelines, and the formulation of health care policy.

AMERICAN COLLEGE OF PREVENTIVE MEDICINE is a national medical society of physicians whose primary interest and expertise are in disease prevention and health promotion. Specialists in preventive medicine are uniquely trained in both clinical medicine and public health. They have skills needed to understand and reduce the risks of disease, disability and death in individuals and in population groups. Physicians trained in preventive medicine work in public health and community agencies, in health care delivery organizations and systems, in primary care settings, in workplaces, and in academia. The College membership (approximately 2,200) constitutes a major national resource of expertise in disease prevention and health

promotion—areas vital to protecting and improving the nation's health.

AMERICAN DENTAL ASSOCIATION (the "Association"), an Illinois not-for-profit corporation founded in 1859, is the leading dental association in the United States with over 140,000 member dentists representing approximately 72% of this nation's active licensed dentists. The stated object of the Association, as set forth in its Constitution, is to "encourage the improvement of the health of the public and to promote the art and science of dentistry." The Association has a vital interest in matters that affect the oral health of the public, and has long been a leader in the battle against tobacco-related disease, working to educate dentists and the public about the adverse oral health effects of tobacco use. Association policy calls for, among other things, legislation or regulation that acknowledges nicotine as an addictive drug and authorizes the FDA to "regulate tobacco products as nicotine delivery devices and/or drugs."

AMERICAN DENTAL HYGIENISTS' ASSOCIATION (ADHA) is the largest national organization representing the professional interests of dental hygienists. Dental hygienists are licensed health professionals dedicated to improving access to oral health care services. As the primary providers of preventive oral health services, including routine prophylaxis; periodontal assessment, treatment and maintenance; application of fluorides and sealants; x-rays; and education in self care, dental hygienists contribute to optimal oral health, a fundamental part of total health. As preventative oral health specialists, dental hygienists know full well the value of prevention. Cigarette and smokeless tobacco use creates serious -- and preventable -- public health problems. FDA regulation of tobacco products will help to prevent tobacco addiction and resulting morbidity and mortality.

AMERICAN HEART ASSOCIATION (AHA) is a nonprofit, voluntary health organization funded by private contributions. AHA's mission is to reduce disability and death from cardiovascular diseases, including heart attack and stroke. AHA is one of the world's premier health organizations, with nearly 2,000 community organizations in the 50 states, Washington, DC, and Puerto Rico. Approximately 4.2 million volunteers work with AHA to fulfill its mission. AHA has long been active before Congress and regulatory agencies on tobacco and health-related matters and has petitioned the FDA on several occasions seeking regulation of cigarettes and other tobacco products under the Food, Drug, and Cosmetic Act. In addition, AHA submitted comments to the FDA on the agency's proposed tobacco regulations.

AMERICAN LUNG ASSOCIATION is the nation's oldest voluntary health organization, with volunteers and affiliates in all 50 states, the District of Columbia, Puerto Rico and the Virgin Islands. The Lung Association includes nearly 400,000 volunteers and more than 10,000 medical professionals, including most of the nation's leading pulmonary physicians, who belong to its medical section, the American Thoracic Society. Cigarette smoking is a major cause of chronic obstructive lung disease. Therefore, the Association has long been active in research, education and public policy advocacy on the adverse health effects of tobacco products. In addition, the Association submitted comments to the FDA on the agency's proposed tobacco regulations.

AMERICAN MEDICAL ASSOCIATION (AMA), with a membership of more than 280,000 physicians, is the largest private nonprofit organization of physicians in the United States. The AMA's mission is to promote the science and art of medicine and the betterment of the public health. The AMA has

long opposed tobacco use, based on the massive body of scientific evidence that tobacco is addictive and kills smokers. The consequences of tobacco use to the public health have been staggering, and the importance of bringing tobacco use under control is correspondingly great. The AMA submitted comments to the FDA on the agency's proposed tobacco regulations.

AMERICAN MEDICAL WOMEN'S ASSOCIATION (AMWA) is a national organization of 10,000 women physicians and physicians-in-training, dedicated to promoting women's health and fostering the woman physician. Founded in 1915, AMWA has physician chapters in 35 states, and student chapters in nearly all of the nation's 144 medical schools. AMWA recognizes that tobacco use is the leading preventable cause of premature death among women and is committed to aggressive action to reduce tobacco use among all Americans. AMWA supports a broad range of progressive tobacco control and prevention policies. In 1994, the organization adopted a position in support of FDA authority to regulate tobacco products.

AMERICAN NURSES ASSOCIATION (ANA) represents the interests of the nation's 2.6 million registered nurses through its 53 constituent state and territorial associations and over 180,000 members. Dedicated to ensuring the availability of an adequate supply of highly-skilled and well-educated nurses, the ANA is committed to meeting the needs of nurses and health care consumers. The ANA advances the nursing profession by fostering high standards of nursing practice, promoting the economic and general welfare of nurses in the workplace, projecting a positive and realistic view of nursing, and lobbying the Congress and regulatory agencies on health care issues affecting nurses and the general public.

AMERICAN PUBLIC HEALTH ASSOCIATION (APHA) is a national organization devoted to the promotion and protection of personal and environmental health. Founded in 1872, APHA is the largest public health organization in the world, representing over 50,000 public health professionals. It represents all disciplines and specialties in public health. APHA passed comprehensive policy calling for full authority of the Food and Drug Administration to regulate tobacco and all tobacco products. APHA continues to advocate for this and other national tobacco control measures to protect the public's health from the adverse effects of tobacco products.

AMERICAN SCHOOL HEALTH ASSOCIATION unites the many professionals working in schools who are committed to safeguarding the health of school-aged children. The Association, a multi-disciplinary organization of administrators, counselors, dentists, health educators, physical educators, school nurses, and school physicians, advocates high-quality school health instruction, health services, and a healthful school environment.

AMERICAN SOCIETY OF ADDICTION MEDICINE (ASAM) is an association of 3,000 physicians dedicated to improving the treatment of alcoholism and other addictions (including addiction to nicotine), educating physicians and medical students, promoting research and prevention, and informing the medical community and the public about addictions, their treatment, and prevention. ASAM believes that nicotine addiction is the most serious addiction problem in the nation because of the vast numbers of people affected and the enormous suffering it causes. ASAM submitted comments to the FDA on the agency's proposed tobacco regulations.

AMERICAN VETERANS COMMITTEE (AVC) was founded during World War II by a group of servicemen and servicewomen who were concerned that the "post-war world" be a more democratic, a more equal, and a more just world. The founders of AVC conceived a unique philosophy for a veterans organization—that of "citizens first, veterans second," dedicated to the proposition that what is good for the nation is good for the veteran.

ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS (ASTHO) is organized as a 501(c)3 non-profit association that represents the public health agencies of each of the United States states and territories. ASTHO is engaged in a wide range of legislative, scientific, educational, and programmatic issues and activities on behalf of public health. ASTHO's mission is to formulate and influence sound national public health policy and to assist state health departments in the development and implementation of programs and policies to promote health and prevent disease.

CHILDREN'S DEFENSE FUND (CDF) works to *Leave No Child Behind®* and to ensure every child a *Healthy Start*, a *Head Start*, a *Fair Start*, a *Safe Start*, and a *Moral Start* in life and successful passage to adulthood with the help of caring families and communities. CDF began in 1973 and is a private, nonprofit organization supported by foundations, corporation grants, and individual donations, and has never taken government funds. CDF provides a strong, effective voice for all the children of America who cannot vote, lobby, or speak for themselves. We pay particular attention to the needs of poor and minority children and those with disabilities. CDF educates the nation about the needs of children and encourages preventive investment before they get sick or into trouble, drop out of school, or suffer family breakdown.

FEDERATION OF BEHAVIORAL, PSYCHOLOGICAL & COGNITIVE SCIENCES, established in 1980, is a coalition of scientific societies. Research interests of federated society members include behavioral, psychological, and cognitive processes and their physiological bases, as well as the application of that research to health, education, and human development. The Federation's goals are to: (1) educate the public and officers of private and public agencies about the need for research on behavior and cognition; (2) provide sources of expertise and knowledge in the behavioral, psychological, and cognitive sciences; (3) encourage legislation and policy that enhance training and research on behavioral, psychological, psychobiological, and cognitive processes; (4) encourage the sound use of science in the creation of public policy; (5) foster effective interaction between both public and private funding agencies and the community of scientists and scientific societies; and (6) facilitate information exchange among constituent societies and establish channels of communication with other scientific organizations.

INFACT is a national grassroots organization whose purpose is to stop life-threatening abuses of transnational corporations and increase their accountability to people around the world.

INTERRELIGIOUS COALITION ON SMOKING OR HEALTH is composed of organizations from all faith traditions. The Coalition is committed to educating religious communities and the wider public on policy initiatives to control tobacco. The Coalition focuses on federal and state policies in the executive and legislative branches of government.

NATIONAL ASSOCIATION OF COUNTY AND CITY HEALTH OFFICIALS (NACCHO) represents the almost 3000 local public health departments - in cities, counties and

townships - who work on the front lines to protect and promote the health of the public. Many local health departments are engaged actively in programs to control tobacco use and restrict youth access to tobacco in their communities, recognizing that tobacco use is the single greatest preventable cause of premature death. NACCHO has been a longstanding proponent of national strategies to control tobacco use, particularly among youth.

NATIONAL CENTER FOR TOBACCO-FREE KIDS works to protect minors from tobacco by raising awareness that tobacco is a pediatric disease, changing public policies to limit the marketing and sales of tobacco to children, and altering the environment in which tobacco use and policy decisions are made. The National Center has over 100 member organizations, including health, civic, corporate, youth, and religious groups dedicated to reducing children's use of tobacco products. In addition, as the Campaign for Tobacco-Free Kids, the Center submitted comments to the FDA on the agency's proposed tobacco regulations.

NATIONAL COUNCIL ON WOMEN'S HEALTH, INC. (NCWH) is a multi-cultural non-profit women's health organization dedicated to developing working partnerships between health professionals and consumers. The organization was founded in 1979. The NCWH was envisioned as an organization that would advance the cause of women's health by bringing together professionals and consumers to learn from each other and to increase public awareness of women's health needs.

NATIONAL ORGANIZATION FOR WOMEN FOUNDATION is a 501(c)(3) organization devoted to furthering women's rights through education and litigation.

NOW Foundation is affiliated with the National Organization for Women, the largest feminist organization in the United States, with a membership of over 500,000 women and men in more than 500 chapters in all 50 states and the District of Columbia. Since its inception in 1986, a major goal of NOW Foundation has been to promote women's health. NOW Foundation conducts educational programs to inform girls and young women about the dangers of tobacco use and emphasizes women's health through its Women's Health Project and annual Love Your Body Day.

NATIONAL TOBACCO INDEPENDENCE CAMPAIGN (NTIC) is a social marketing enterprise in support of diversity in the tobacco-control movement. NTIC is designed to help unite people around issues related to healthier lifestyles, free of tobacco use. NTIC focusses on the policy aspects of tobacco control; encourages racial, ethnic, and gender inclusiveness in service communities; and assists targeted outreach through individual initiatives unique to demographic segments of distinct ethnic groups that are dependent on tobacco products or financial support from the tobacco industry. With tobacco independence (through cessation or abstinence) as the ideal, and controlled use of tobacco as an important secondary goal, NTIC programs and services provide support to a wide range of communities.

NATIONAL WOMEN'S LAW CENTER is a nonprofit organization that has been working since 1972 to advance and protect women's legal rights. The Center focuses on major policy areas of importance to women and their families including child support, employment, education, reproductive rights and health, child and adult dependent care, public assistance, tax reform, and social security, with special attention given to the concerns of low income women.

ONCOLOGY NURSING SOCIETY (ONS) works to promote excellence in oncology nursing by promoting the highest professional standards of oncology nursing; studying, researching, and exchanging information, experiences, and ideas leading to improved oncology nursing; encouraging nurses to specialize in the practice of oncology nursing; fostering the professional development of oncology nurses, individually and collectively; and fostering a culturally diverse organization that is responsive to the changing needs of ONS members and the populations they represent and serve

PARTNERSHIP FOR PREVENTION is a national nonprofit organization whose mission is to increase the priority, resources, knowledge, and incentives for disease prevention and health promotion policies and practices. The organization adheres to the highest standards of scientific evidence supporting the case for preventive services, health promotion, and environmental health. Its members include leading corporations, professional and trade associations, and state health departments.

SUMMIT HEALTH COALITION is the nation's largest network of primarily African American organizations focusing on health policy issues. Summit works on behalf of African American consumers and providers, as well as other underserved populations, so that they might be better served by health care policies and the changing health care system. Summit was established in 1993. Its members are comprised of over 50 national, state, and community-based organizations.

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In The
Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, et al.,
Petitioners,
v.

BROWN AND WILLIAMSON TOBACCO CORP., et al.,
Respondents.

On Writ Of Certiorari To The
United States Court Of Appeals
For The Fourth Circuit

BRIEF OF THE STATES OF MINNESOTA, ALASKA,
ARIZONA, ARKANSAS, CALIFORNIA, COLORADO,
CONNECTICUT, FLORIDA, HAWAII, IDAHO,
ILLINOIS, INDIANA, IOWA, KANSAS, MAINE,
MARYLAND, MASSACHUSETTS, MICHIGAN,
MISSISSIPPI, MISSOURI, MONTANA, NEVADA,
NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO,
NEW YORK, NORTH DAKOTA, OHIO,
OKLAHOMA, OREGON, PENNSYLVANIA, RHODE
ISLAND, SOUTH DAKOTA, TEXAS, UTAH,
VERMONT, WASHINGTON, WEST VIRGINIA,
WISCONSIN, WYOMING, AND CITY AND
COUNTY OF SAN FRANCISCO AS AMICI CURIAE
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INTEREST OF THE AMICI STATES

The forty Amici States and the City and County of San Francisco submit this brief in support of the regulations promulgated by the U.S. Food and Drug Administration (FDA) restricting the promotion and sale of tobacco products to minors. The Amici States seek reversal of the Fourth Circuit's decision that the FDA does not have jurisdiction under the Food, Drug and Cosmetic Act (FDCA) to regulate tobacco products.

The question of whether the FDA has jurisdiction to regulate tobacco products under the FDCA is vitally important to the States. This Court has often recognized the States' responsibility to promote the health, safety and welfare of their citizens. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996); *Barsky v. Board of Regents*, 347 U.S. 442, 449 (1954).

Tobacco products dramatically affect this state interest. Every day, 3,000 American children start using tobacco regularly. Fully one-third of those who continue using tobacco products will suffer from painful, debilitating tobacco-related diseases including lung cancer, oral cancer, throat cancer, bladder cancer, cancer of the esophagus, cancer of the pancreas, heart disease, and chronic obstructive pulmonary disease. Millions of people in this country suffer from these diseases, and die prematurely, because they became addicted to the drug nicotine in the tobacco products they began to use as children. Over 400,000 individuals die each year from tobacco-related diseases – the equivalent of three fully loaded 747s crashing every day, 365 days a year, with no survivors.

The Amici States have made important strides in limiting tobacco use by minors. These States and many local governments have enacted laws designed to prevent young people from using tobacco products. In addition, more than forty state Attorneys General have recently sued the tobacco industry under state laws in their respective state courts. These lawsuits convincingly demonstrated the decades-long conspiracy by the tobacco industry to conceal the deadly and addictive nature of its products. The recent agreements between the States and the nation's five largest tobacco companies settling the States' tobacco litigation achieve important advances in the effort to combat youth smoking. Despite the important achievements of the Amici States, however, tobacco use by young people is on the rise.

The FDA rules at issue here are therefore necessary to complement and supplement the efforts of the States and local governments. These rules – which are directed at the use of tobacco products by young people – cover important ground that the agreements settling the States' tobacco litigation did not and could not address.¹ The FDA's regulations are fully authorized by law and perform a critical role in the comprehensive federal, state and local effort needed to prevent children from using

¹ The terms of the recent settlement between forty-six states, five territories and the District of Columbia and the nation's five largest tobacco companies are contained on the website maintained by the National Association of Attorneys General. See <<http://www.naag.org/tob2.htm>>. Seventeen companies have joined as additional parties to the agreement. The States of Minnesota, Florida, Texas and Mississippi had previously settled their claims against the tobacco companies.

and becoming addicted to the drug nicotine in tobacco products. For the reasons set forth below, those regulations are valid and should be upheld by this Court.

SUMMARY OF ARGUMENT

This Court should reverse the Fourth Circuit's decision, and should hold that the FDA has jurisdiction under the FDCA to regulate tobacco products. This case is of enormous public importance. The regulations at issue address the number one preventable public health problem of our time. The FDA's regulations address matters that cannot be effectively addressed by the States alone. The Fourth Circuit's decision that the FDA lacks the authority to regulate tobacco products as drug delivery devices misconstrues the authority granted to the FDA under the FDCA and impedes the FDA from joining the States in fully addressing this significant public health problem.

The Fourth Circuit's decision misapplies important, well-settled principles of administrative law that require deference to the FDA's judgment and permit the FDA to determine which products fit within the broad statutory framework for regulation of "drugs" and "devices" under the FDCA. The circuit court substituted its judgment for that of the FDA, and essentially ignored the compelling – but until recently secret – evidence from the tobacco industry's own files relied upon by the FDA in asserting jurisdiction over tobacco products.

This evidence overwhelmingly shows, as Judge Hall found in his dissent, "that the companies have known

about the addictive qualities of their products for years and that cigarettes are deliberately manipulated to create and sustain addiction to nicotine." Pet. App. 58a (Hall, J., dissenting). Additional evidence the States obtained through their own litigation further exposed the industry's knowledge that its products fall squarely within the FDA's jurisdiction. Again, in the words of Judge Hall's dissent, "the strength of nicotine's addictive qualities, the extent of the health problems created by tobacco products, and the complicity of the manufacturers bring us to a different place than we have been before." Pet. App. 59a.

Finally, the Fourth Circuit's decision fundamentally misconstrues the relationship between the States and the federal government. The States have enacted laws to prevent young people from using tobacco. The States also have an important role to play in implementing the Alcohol, Drug Abuse and Mental Health Administration Reorganization Act enacted by Congress in 1992. However, the federal government, through the FDA, has a vital role to play in both limiting youth access to tobacco and restricting advertising that appeals to young people. Contrary to the circuit court's conclusion, FDA regulation of tobacco products is fully authorized by the FDCA and performs a critical function in the comprehensive effort needed to address this important public health issue.

ARGUMENT

I. The Food And Drug Administration Has Jurisdiction To Regulate Nicotine And Tobacco Products.

The FDA's authority to regulate tobacco products is supported by well-established administrative law that requires deference to agency judgment and permits the FDA to change its position based on new information or for other sound reasons. There is no dispute that Congress has delegated to the FDA the responsibility to determine which specific products are subject to regulation under the FDCA. After an exhaustive and extensive review of a voluminous record, the FDA properly concluded that nicotine-containing tobacco products are drug delivery devices which are subject to regulation. Under long-standing principles of agency law, that conclusion is entitled to deference. *Chevron, U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 844 (1984).

An important part of the current debate about the FDA's jurisdiction over tobacco products centers on the meaning of the term "intent" in the FDCA. The FDCA provides that a drug or device is an article "intended to affect the structure or any function of the body." 21 U.S.C. §§ 321(g)(1)(C), 321(h)(3) (emphasis added). The industry claims that intent cannot be established absent marketing claims by the industry that its products have a medical or health benefit.² Yet nothing in the language of the FDCA

² The industry does not dispute that the FDA has jurisdiction over tobacco products marketed with health claims. Pet. App. 80a n.3 ("Plaintiffs do not dispute that FDA has authority to regulate tobacco products marketed as providing

limits the FDA to considering only express marketing claims in determining whether a product is "intended to affect the structure or any function of the body."

The FDA's assertion of jurisdiction over tobacco products is fully consistent with its statutory authority. The FDA has the authority under the FDCA to regulate drugs³ and devices.⁴ And Congress has delegated to the FDA, and not the courts, the responsibility to determine, based on the evidence, which specific products meet the statutory definitions. The FDA properly determined that, irrespective of the industry's marketing claims, tobacco products fall within the statutory standards for both "drug" and "device," and are therefore subject to regulation under the FDCA. The FDA's jurisdictional determination was based on an overwhelming factual record

medical or other health benefits."). The lower federal courts have long recognized the FDA's jurisdiction to regulate tobacco products marketed as providing a health benefit. See *United States v. 354 Bulk Cartons, Etc.*, 178 F. Supp. 847 (D.N.J. 1959) (Trim cigarettes are drugs within the meaning of the FDCA); *United States v. 46 Cartons, Etc.*, 113 F. Supp. 336 (D.N.J. 1953) (Fairfax cigarettes are drugs within the meaning of the FDCA).

³ The term "drug" is defined to include not only "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," but also "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1).

⁴ The term "device" includes "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article . . . intended to affect the structure or any function of the body of man or other animals . . . and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h).

demonstrating that nicotine is a drug, and that the tobacco manufacturers deliberately design and market their products to promote the addictive properties of nicotine. See, e.g., *Jurisdictional Determination*, 61 Fed. Reg. 44,396, 44,854-994 (1996); *Jurisdictional Analysis*, 60 Fed. Reg. 41,453, 41,583-784 (1995). As the FDA explained in the rulemaking record, "[t]he quality, quantity, and scope of the evidence available to FDA today is far greater than any other time when FDA has considered regulation of cigarettes and smokeless tobacco products." 60 Fed. Reg. at 41,464 n.1.

While the administrative record is more than sufficient to support FDA jurisdiction, additional previously secret information discovered in the suits by the Amici States against the tobacco industry unequivocally demonstrates that the industry intends that its products affect the structure and function of the body, and that the industry manipulates and controls the nicotine levels in tobacco products to achieve and maintain addiction. Minnesota's case alone produced over 33 million pages of documents in depositories in Minnesota and England, as well as approximately 40,000 more documents over which the industry had improperly claimed an attorney-client privilege.⁵ A recently published article in the *Journal of the American Medical Association* sets forth many representative tobacco industry documents relating to the

⁵ The tobacco manufacturers and tobacco-related organizations that are parties to the recent national settlement with many of the Amici States have agreed to maintain internet document websites accessible through "<<http://www.tobacco-archives.com>>" where documents produced in the States' litigation will be accessible to the public.

issues of addiction, cigarette design and nicotine manipulation.⁶ The authors conclude, based on their review of thousands of pages of industry documents, that the industry knew for decades of the addictiveness of nicotine and perpetuated that addiction through manipulation of nicotine.⁷

Several of the exhibits in Minnesota's trial against the industry, discussed in the JAMA article, illustrate the industry's true intent:

- A "CONFIDENTIAL" 1969 memo written by W.L. Dunn (known within the industry as "The Nicotine Kid") to Philip Morris research director Dr. Helmut Wakeham:

I would be more cautious in using the pharmonic-medical model - do we really want to tout cigarette smoke as a drug? *It is, of course, but there are dangerous FDA implications to having such conceptualization go beyond these walls.*⁸

- A "CONFIDENTIAL" Research Planning Memorandum written in 1972 by Claude E. Teague, Jr., assistant director of research at R.J. Reynolds, entitled "The Nature of the Tobacco Business and the Crucial Role of Nicotine Therein":

⁶ See Richard D. Hurt, M.D. & Channing R. Robertson, Ph.D., *Prying Open the Door to the Tobacco Industry's Secrets About Nicotine: The Minnesota Tobacco Trial*, 280 JAMA 1173 (1998) ("Hurt & Robertson").

⁷ *Id.* at 1180.

⁸ *Id.* at 1176 (emphasis added).

In a sense, the tobacco industry may be thought of as being a specialized, highly ritualized and stylized segment of the pharmaceutical industry. Tobacco products, uniquely, contain and deliver nicotine, a potent drug with a variety of physiological effects. . . . Thus a tobacco product is, in essence, a vehicle for delivery of nicotine, designed to deliver the nicotine in a generally acceptable and attractive form. Our Industry is then based upon design, manufacture and sale of attractive dosage forms of nicotine, and our Company's position in our Industry is determined by our ability to produce dosage forms of nicotine which have more overall value, tangible or intangible, to the consumer than those of our competitors.⁹

- A 1972 Philip Morris memorandum summarizing the discussion at a conference attended by 25 scientists from England, Canada and the United States:

The majority of conferees would accept the proposition that nicotine is the active constituent of cigarette smoke. . . . The cigarette should be conceived not as a product but as a package. The product is nicotine. Think of the cigarette pack as a storage container for a day's supply of nicotine. . . . Think of the cigarette as a dispenser for a dose unit of nicotine. . . .

⁹ *Id.* at 1175 (emphasis added). This document was cited by the FDA in support of its regulation of tobacco products. See 60 Fed. Reg. 41,453, 41,617-18 (1995) (quoting from New York Times newspaper report).

Think of a puff of smoke as the vehicle of nicotine. . . . Smoke is beyond question the most optimized vehicle of nicotine and the cigarette the most optimized dispenser of smoke.¹⁰

These documents, and many others like them, unequivocally demonstrate the true intent and understanding of the tobacco industry. The tobacco companies understood a long time ago that "we are in a nicotine rather than a tobacco industry,"¹¹ and at least one has suggested that it "should learn to look at itself as a drug company rather than as a tobacco company."¹² To suggest that the FDA is without jurisdiction to regulate simply because the industry deliberately failed to publicly acknowledge its true intent would reward the industry for decades of deception and deceit. Such a result would be contrary to public policy. Instead, this Court should broadly construe the FDCA to achieve its purpose of protecting public health. See *United States v. An Article of Drug*, 394 U.S. 784, 798 (1969) ("Congress fully intended that the Act's coverage be as broad as its literal language indicates - and equally clearly, broader than any strict medical definition might otherwise allow. . . . [W]e are all the more convinced that we must give effect to congressional intent in view of the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent

¹⁰ Hurt & Robertson, *supra* n.6 at 1176; 60 Fed. Reg. 41,453, 41,617 (1995).

¹¹ Hurt & Robertson, *supra* n.6 at 1176.

¹² *Id.*

with the Act's overriding purpose to protect the public health.").

Regulation of tobacco products is no different than FDA regulation of the many other drugs and devices which are, in the language of the FDCA, "intended to affect the structure or function of the body." While tobacco products may be "different from the run-of-the-mine drugs and devices in the FDA's bailiwick," Pet. App. 74a (Hall, J., dissenting),

the FDCA was broadly worded by design. In an area in which complex new products (and old products, seen in the light of new evidence) pose the potential for grievous harm, Congress deemed it necessary to delegate to an expert - the FDA - the job of monitoring drugs. Cigarettes and smokeless tobacco clearly fit within the literal terms of the FDCA. Absent a showing that following these statutory terms would be absurd or somehow frustrate congressional intent, [the Court is] bound to uphold FDA jurisdiction.

Id. at 70a-71a.

The FDA's well-reasoned and extensively documented basis for regulating tobacco products is entitled to deference. *Chevron, U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 844 (1984) ("We have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer"). The Fourth Circuit erroneously substituted its own judgment as to whether tobacco products are subject to regulation rather than

upholding the FDA's permissible and well-reasoned construction of the statute. See *Regions Hosp. v. Shalala*, 118 S. Ct. 909, 915 (1998) ("If the agency's reading fills a gap or defines a term in a reasonable way in light of the Legislature's design, we give that reading controlling weight, even if it is not the answer 'the court would have reached if the question initially had arisen in a judicial proceeding.'"), citing *Chevron*, 467 U.S. at 843.

Moreover, that the FDA chose not to regulate tobacco products without express marketing claims sooner does not preclude it from doing so now. "An initial agency interpretation is not instantly carved in stone. On the contrary, the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis." *Id.* at 863-64; *Rust v. Sullivan*, 500 U.S. 173, 186-87 (1991) ("An agency is not required 'to establish rules of conduct to last forever,' . . . but rather 'must be given ample latitude to adapt its rules and policies to the demands of changing circumstances.'" (citations omitted)). The court in *Action On Smoking And Health v. Harris*, 655 F.2d 236 (D.C. Cir. 1980), while upholding the FDA's decision not to exercise jurisdiction over tobacco products at that time, recognized that the agency was free to change its position:

Nothing in this opinion should suggest that the Administration is irrevocably bound by any long-standing interpretation and representations thereof to the legislative branch. An administrative agency is clearly free to revise its interpretations.

Id. at 242 n.10;¹³ accord *Banzhaf v. FCC*, 405 F.2d 1082, 1090 n.26 (D.C. Cir. 1968) ("Nor do we think the FCC's 1964 disclaimer of intent to deal with the cigarette problem deprives it of authority it would otherwise have had to do so now.").

In addition to being contrary to law, the industry's argument that the FDA should be precluded from regulating nicotine-containing tobacco products because it previously declined to do so rings hollow in view of the industry's history of deception. The change in the FDA's position concerning regulation of the drug nicotine and tobacco products is based in part upon compelling new evidence from the tobacco industry's heretofore secret internal files. If the government had known earlier what the industry knew and conspired to conceal for years – about the addictiveness of nicotine in tobacco products, about the industry's efforts to manipulate levels of nicotine, and about the industry's efforts to target young people – the FDA may well have acted much sooner.

The Amici States urge this Court to reverse the Fourth Circuit's decision precluding the FDA from responding to new evidence to regulate tobacco products because, in the words of Judge Hall's dissent, "the 'cold hard facts' are now in." Pet. App. 64a.

¹³ The court in *Harris* was also careful to note that it was expressing "no opinion on the question of FDA jurisdiction over cigarettes or cigarette filters as 'medical devices.'" *Harris*, 655 F.2d at 237 n.4. As this Court is aware, this is part of the basis upon which the FDA is currently asserting jurisdiction over tobacco products.

II. The Fourth Circuit's Decision Fundamentally Misconstrues The Impact Of State Regulation Of Tobacco Products: The Law Permits, And The Problem Demands, A Comprehensive Federal, State And Local Effort.

This Court should reverse the Fourth Circuit's decision because the lower court misconceives the relationship between the States and the federal government. The Fourth Circuit found that Congress, through the Alcohol, Drug Abuse and Mental Health Administration Reorganization Act of 1992 (ADAMHA amendments), expressed "clear congressional intent that States exercise their traditional police powers and take a primary role in attacking the problem of youth access to tobacco products." Pet. App. 51a. The court concluded that the FDA lacks jurisdiction over tobacco because there is an "inherent conflict" between the FDA's regulations and the primary state regulatory role allegedly established in the ADAMHA amendments. *Id.*

The circuit court's analysis that the FDA's regulations conflict with the ADAMHA amendments is flawed for several reasons. First, as the district court and the dissenting judge at the Fourth Circuit properly observed, the ADAMHA amendments merely establish conditions for the receipt of federal funds; they "do not represent an all-encompassing last-word pronouncement of federal policy on underage smoking." Pet. App. 100a, 69a-70a. The ADAMHA amendments condition future federal substance abuse prevention and treatment block grants on each State having in effect a law prohibiting the sale or distribution of tobacco products to individuals under the age of 18. 42 U.S.C. § 300x-26(a)(1). The amendments

further condition such grants on each State having a program to annually conduct random, unannounced inspections to ensure compliance with the law. The amendments require each State to submit an annual report to the Secretary of Health and Human Services (HHS) describing the State's efforts to enforce the law, the State's success rate, and the additional enforcement efforts the State will take in the future. 42 U.S.C. § 300x-26(b).

The FDA is not precluded from regulating within its sphere of authority simply because Congress has also given the States a direct role to play in regulating the illegal use of tobacco by minors. The FDA's regulations and the ADAMHA amendments have an entirely different focus. The ADAMHA amendments are targeted at the States. The FDA regulations, on the other hand, are targeted at the tobacco industry and retailers. The ADAMHA amendments and the FDA regulations attack a pervasive national problem from different perspectives:

While this final rule [implementing the ADAMHA amendments] is directed to the States and the FDA proposal focuses on the tobacco industry and retailers, they are both designed to help address the serious public health problem caused by young people's use of and addiction to nicotine-containing tobacco products. By approaching this public health problem from different perspectives, these actions together would help achieve the President's goal of reducing the number of young people who use tobacco products.

Second, the tobacco industry argues here that the "comprehensiveness" of the regulatory scheme enacted by Congress and the role provided for the States under the ADAMHA amendments precludes the FDA from regulating. The industry has made a similar argument for years, more typically when it is asserting that the *States* are precluded from regulating. See, e.g., *Philip Morris, Inc. v. Harshbarger*, 122 F.3d 58, 80 (1st Cir. 1997) ("In sum, [the tobacco manufacturers] argue that the very comprehensiveness, complexity, and specificity of the federal reporting provisions evince a federal dominance and pervasiveness in ingredient reporting and disclosure that allows no room for supplemental state laws such as the Disclosure Act. Ultimately, we find the manufacturers' arguments unpersuasive."). The industry has also frequently argued in private suits that state regulatory and common law is preempted by specific preemption provisions contained in federal law. In *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), however, this Court noted the limited nature of the preemption provision in the Public Health Cigarette Smoking Act of 1969 in holding that not all of the state tort claims at issue were preempted.¹⁴ As in these earlier cases, the tobacco industry's

¹⁴ Lower courts have likewise rejected the argument that legislation enacted by Congress precludes additional state regulation of tobacco products. See, e.g., *Philip Morris, Inc. v. Harshbarger*, 122 F.3d 58 (1st Cir. 1997); *Penn Advertising of Baltimore v. Mayor and City Council*, 63 F.3d 1318 (4th Cir. 1995) (Baltimore ordinance prohibiting placement of any sign that advertises cigarettes in a publicly visible location not preempted by federal law), *vacated and remanded on other grounds*, 518 U.S. 1030 (1996), *aff'd on remand*, 101 F.3d 332 (4th Cir. 1996), *cert. denied*, 520 U.S. 1204 (1997); see also *Banzhaf v.*

"comprehensive regulatory scheme" argument also fails here.

Third, there is no reasonable basis to conclude that the FDA regulations leave no room for state regulation of tobacco products. Under 21 U.S.C. § 360k, only state regulations that are different from or in addition to specific FDA requirements are preempted. The FDA has provided numerous examples of state regulations that will not be preempted by its rule, including restrictions on the sale or distribution of tobacco products, restrictions on smoking in public places, penalties on underage smokers and age restrictions on persons who sell tobacco. See 61 Fed. Reg. 44,396, 44,549 (1996). This Court has frequently noted the presumption against the preemption of state police power regulations. See *Medtronic v. Lohr*, 518 U.S. 470, 485 (1996). Even those state laws that might be preempted could qualify for exemption, thereby further minimizing conflicts. See 61 Fed. Reg. 44,396, 44,548-50; 21 U.S.C. § 360k(b). The FDA has stated that its regulations set only a floor for regulation of youth access to tobacco products, and that "[f]ederal cooperation with, and continued reliance upon, innovative and aggressive state and local enforcement efforts is essential." 61 Fed. Reg. at 44,548. Indeed, on November 28, 1997, the FDA published a final rule granting exemptions to Alabama,

FCC, 405 F.2d 1082, 1089 (D.C. Cir. 1968) ("Nothing in the [Federal Cigarette Labeling and Advertising Act of 1965] indicates that Congress had any intent at all with respect to other types of regulation by other agencies – much less that it specifically meant to foreclose all such regulation. If it meant to do anything so dramatic, it might reasonably be expected to have said so directly").

Alaska, and Utah, permitting them to enforce their more stringent age requirements. *See* 62 Fed. Reg. 63,271.

Finally, while the States have done a great deal to address the problems of tobacco use, federal food and drug regulation has co-existed with state regulation for years. Although the States unquestionably play an essential role in regulating matters pertaining to public health and safety, the federal government also has a very significant role. *See Medtronic*, 518 U.S. at 475 ("Despite the prominence of the States in matters of public health and safety, in recent decades the Federal Government has played an increasingly significant role in the protection of the health of our people."). The general design of food and drug regulation allows for complementary state and federal jurisdiction. The circuit courts have recognized this complementary jurisdiction in holding that, while the FDCA is important in setting uniform national standards, the act does not preclude the States from also regulating products subject to FDA authority.¹⁵ This Court has previously rejected arguments that regulation under the FDCA infringes upon the role of the States in regulating matters pertaining to public health and safety. *See United States v. Sullivan*, 332 U.S. 689, 697 (1948) (rejecting claim

¹⁵ *See, e.g., Smith v. Pingree*, 651 F.2d 1021, 1025 (5th Cir. 1981) (FDCA does not preempt Florida statute concerning the fitting and selling of hearing aids. "Because the federal requirements did not regulate every aspect of this area, the state had the implied reservation of power to fill out the scheme."); *Pharmaceutical Soc. of State of New York, Inc. v. Lefkowitz*, 586 F.2d 953, 958 (2d Cir. 1978) (State law not preempted by the FDCA. "The [FDCA] is not so pervasive as to remove the states entirely from the field of drug regulation.").

that application of FDCA infringes upon powers reserved to the States).

Tobacco use by minors is a pervasive national problem that must be addressed by comprehensive regulation at the federal, state and local level. Unlike the Respondents, the federal government recognizes the need for a comprehensive effort to combat tobacco use by minors:

The outcome, however, will depend on the nature and extent of the enforcement actions taken by the States [implementing the ADAMHA amendments] and, if the FDA proposed restrictions on access and appeal were made final, the synergistic effect such efforts would have when combined with such additional control measures, and with any supplemental tobacco control measures the States may adopt.

61 Fed. Reg. 1492, 1501 (1996).¹⁶ "An overlap between two regulatory systems does not require wholesale jettisoning of one in favor of the other." Pet. App. 70a (Hall, J., dissenting).

The FDA's authority to regulate tobacco products is authorized by law, and is a critically important part of the effort to limit the use of tobacco products by minors. The FDA regulations constitute uniform national standards that the States may build upon. Given the magnitude of

¹⁶ HHS recognizes that local governments also have a role to play: "[T]he Federal statute [ADAMHA] and regulation are minimum requirements to which the States are held. In no way should they be considered as limiting, or requiring States to limit, the powers of local governments to enact or enforce tobacco control laws." 61 Fed. Reg. 1492, 1496 (1996).

the problem, the ADAMHA amendments alone are not enough. The amendments address only the issue of youth *access* to tobacco products. More is needed, including advertising and promotion restrictions, restrictions on retailers, and additional educational efforts directed at children. The FDA regulations are an important step in the right direction. When combined with the ADAMHA amendments and other federal laws, current laws at the state and local level, the advances achieved through state litigation against the tobacco industry, and additional efforts to be undertaken in the future, the FDA's regulations will help limit the number of American youth who become addicted to nicotine. Millions of individuals will benefit, both now and in the future.

◆

CONCLUSION

For the foregoing reasons, the decision of the Fourth Circuit should be reversed.

July 1999

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In the
Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, *et al.*,
Petitioners,

v.

BROWN AND WILLIAMSON TOBACCO CORP., *et al.*,
Respondents.

On Writ of Certiorari to the United States
Court of Appeals for the Fourth Circuit

**BRIEF AMICUS CURIAE OF PACIFIC LEGAL
FOUNDATION IN SUPPORT OF AFFIRMANCE**

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QUESTION PRESENTED

Does the Food and Drug Administration have statutory jurisdiction to regulate all tobacco products as drugs or devices under the Federal Food, Drug and Cosmetic Act of 1938?

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INTEREST OF AMICUS CURIAE

Pursuant to Supreme Court Rule 37, consent to file this brief was received from all parties and lodged with the Clerk of this Court.¹

Pacific Legal Foundation is the largest and most experienced nonprofit public interest law foundation of its kind in America. Founded in 1973, PLF provides a voice in the courts for mainstream Americans who believe in limited government, private property rights, individual freedom, and free enterprise. PLF litigates nationwide in state and federal courts with the support of thousands of citizens from coast to coast. PLF is headquartered in Sacramento, California, and has offices in Miami, Florida; Honolulu, Hawaii; Bellevue, Washington; and a liaison office in Anchorage, Alaska.

PLF has participated in numerous cases concerning the scope of federal agency authority. For example, PLF participated as amicus curiae before this Court in *Babbitt v. Sweet Home Chapter of Communities for a Greater Oregon*, 515 U.S. 687 (1995); and *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984); and before the United States Courts of Appeals in *National Mining Association v. United States Army Corps of Engineers*, 145 F.3d 1399 (D.C. Cir. 1998).

PLF seeks to augment the arguments of Respondents by elucidating the limitations on federal agency power under administrative law principles. PLF believes its public policy perspective and litigation experience dealing with administrative law issues will provide an additional viewpoint on the legal issues presented.

¹ Pursuant to Supreme Court Rule 37.6, Amicus Curiae Pacific Legal Foundation affirms that no counsel for any party in this case authored this brief in whole or in part; and, furthermore, that no person or entity has made a monetary contribution specifically for the preparation or submission of this brief.

STATEMENT OF THE CASE

On August 28, 1996, the Food and Drug Administration (FDA) published a final rule in the Federal Register, "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents," 61 Fed. Reg. 44,395 (1996). Subsequently, the Respondents filed this suit challenging FDA's exercise of jurisdiction over tobacco products. The United States District Court for the Middle District of North Carolina rejected the challenge, finding that Congress did not intend "to withhold from FDA" the authority to regulate tobacco. *Coyne Beahm, Inc. v. United States Food and Drug Administration*, 966 F. Supp. 1374, 1387 (M.D. N.C. 1997). The United States Court of Appeals for the Fourth Circuit reversed. *Brown & Williamson Tobacco Corp. v. Food & Drug Administration*, 153 F.3d 155 (4th Cir. 1998).

The Fourth Circuit's opinion was based on two rationales. First, notwithstanding the provisions of the Food, Drug and Cosmetic Act (Act) defining "drugs" and "devices," FDA's regulation was inconsistent with the Act as a whole. Because FDA did not and could not comply with the statutory mandates of the Act in its treatment of tobacco, Congress could not have intended that Act, or FDA's administration of it, to apply to tobacco products. Second, FDA's assertion of jurisdiction could not be meshed with congressional intent as to the Act, or with the regulatory scheme created by Congress through statutes directed specifically at tobacco products. FDA petitioned for a writ of certiorari to resolve this important question, which this Court granted.

SUMMARY OF ARGUMENT

As FDA and its Amici ably illustrate, the importance of national tobacco policy is difficult to understate. The production, sale, and export of tobacco products has significant impacts on our national economy and on the health of American citizens. But it is the very significance of the issue that

demonstrates that national tobacco policy properly belongs in the open halls of a democratically elected Congress. FDA's interjection of itself into this issue of broad national policy intrudes into an area Congress reserved to itself. FDA's role is limited to the application of congressional policy; it has no power to establish it.

FDA's decision to recast the contours of its own jurisdiction under an existing federal statute is entitled to no deference. FDA's arguments to the contrary not only rely upon a crabbed interpretation of this Court's decision in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, but also utterly ignore this Court's repeated pronouncements that an agency's determination of its own jurisdiction is not entitled to deference, particularly where, as here, the agency redrafts its jurisdiction in a way that upsets long-settled agency practice without sufficient reason.

ARGUMENT

I

THE SIGNIFICANT ECONOMIC AND PUBLIC HEALTH IMPACTS OF TOBACCO DEMONSTRATE, BY THEMSELVES, THAT TOBACCO REGULATION IS A MATTER OF NATIONAL POLICY THAT MUST BE ESTABLISHED BY CONGRESS, NOT THROUGH THE UNILATERAL DECISION OF FDA

As comprehensively demonstrated by FDA, national tobacco policy plays a major role in the economic life and physiological welfare of United States citizens. Consequently, the issue in this case is not, as FDA would have it, whether tobacco products are "drugs" or "devices" within the meaning of the Food, Drug and Cosmetic Act, 21 U.S.C. 301, *et seq.* The issue in this case is whether national policy on a matter of such obvious public importance ought to be dictated by FDA, or should instead emanate from Congress, "the governmental body

best suited and most obligated to make the choice confronting us in this litigation." *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 672 (1980) (Rehnquist, J., concurring in the judgment).

Congress has the resources and the power to inform itself, and is the appropriate forum where the conflicting pros and cons should have been presented and considered.

United States v. Robel, 389 U.S. 258, 276 (1967) (Brennan, J., concurring in the result). Instead, the pros and cons of national tobacco policy have been weighed here by FDA, an administrative agency that has suddenly decided to redefine its statutory jurisdiction under a federal law in which the jurisdictional provisions have remained more or less fixed since 1938.

FDA admits that it sought to interject itself into national tobacco policy through the implementation of the regulations at issue because the agency believed that the country, as a whole, needed a more forceful anti-tobacco policy:

The [FDA] is proposing new regulations . . . in order to address the serious public health problems caused by the use of and addiction to [tobacco] products.

60 Fed. Reg. 41,313, 41,314 (1995).

FDA's Proposed Rule repeatedly manifested the agency's perception that existing state and federal regulations were not effective *enough* in curbing tobacco use by youths. For example, it acknowledged that "all States prohibit the sale of tobacco products to persons under the age of 18," *id.* at 41,315, consistent with the Alcohol, Drug Abuse and Mental Health Administration Reorganization Act, *id.* at 41,323, but contended that such state laws were not being effectively enforced, *id.* at 41,315. It elsewhere indicated that existing federal laws already addressed tobacco product advertising, and even that its

own regulations encountered preemption issues and potential conflict problems from other federal acts, *id.* at 41,314, 41,319, but the agency proceeded to propose advertising regulations. *Id.* at 41,315. In general, FDA indicated its awareness of other tobacco-specific legislation by asserting that the Proposed Rule was arrived at after FDA "examined many domestic and foreign tobacco control statutes, regulations, and legislation." *Id.* at 41,315. FDA nevertheless concluded:

The agency has examined many options for reducing tobacco use by children and adolescents, *and believes that an effective program must address the following two areas:* (1) Restrictions on cigarette and smokeless tobacco sales that will make these products less accessible to young people; and (2) restrictions on labeling and advertising to help reduce the appeal of tobacco products to young people along with requirements for a manufacturer-funded national education campaign aimed at those under 18 years of age to help reduce the products' appeal to these young people.

Id.

For example, FDA acknowledged that Congress had specifically enacted the Comprehensive Smokeless Tobacco Health Education Act to discourage young people from using smokeless tobacco. And even though it stated that there were 3 million users under the age of 21 of smokeless tobacco in 1986 when Congress passed that legislation, *id.* at 41,317, and 1 million adolescent males who used smokeless tobacco today, *id.* at 41,314 (use of smokeless tobacco by girls is not extensive, *id.* at 41,341), it concluded that Act was not achieving its goal:

Despite the Smokeless Act and State laws prohibiting sales to minors, a high percentage of persons under the age of 18 use smokeless tobacco products.

Id. As a result,

[t]he recent and very large increase in the use of smokeless tobacco products by young people and the addictive nature of these products has persuaded the agency that these products must be included in any regulatory approach that is designed to help prevent future generations of young people from becoming addicted to nicotine-containing tobacco products.

Id. at 41,318. Despite FDA's recognition of the fact that Congress had taken affirmative steps to curb the use of smokeless tobacco by young people, FDA was "persuaded" that Congress' efforts were not having as dramatic an impact as its own regulations would.

Without any prior history of regulating smokeless tobacco or cigarettes, FDA developed what it believed were more effective regulatory means to reduce tobacco use by young people, even though no congressional legislation had delegated any such authority to FDA. FDA's avowed purpose for its rule was to meet the goals announced in a Department of Health and Human Services Report, "Healthy People 2000":

The objective of the proposed rule is to meet the goal of the report "Healthy People 2000" by reducing roughly by half children's and adolescents' use of tobacco products. If this objective is not met within seven years of the date of publication of the final rule, the agency will take additional measures to help achieve the reduction in the use of tobacco products by young people.

Id. at 41,314. The Proposed Rule specifically stated that the Rule "would not restrict the use of tobacco products by adults."

Id. As conceded by FDA, the primary impetus for the rule was not the implementation of the Food, Drug and Cosmetic Act (the purpose of which is to regulate drugs as a whole, and does

not specify that the agency's mandate has any special force with respect to young people), but to meet the "outcome-based" quantitative health goals outlined in an executive agency report. *Id.* at 41,314. Thus, even though Congress created the Substance Abuse and Mental Health Services Administration to carry out a program of state-operated regulatory programs, FDA argued:

FDA strongly supports the basic *objectives* of this program, but believes that their full *achievement* would demand a broad arsenal of controls; including industry programs to complement and fortify the new State inspectional programs.

Id. at 41,362 (emphasis added). FDA's language indicated that it had concluded that the means chosen by the congressional scheme were inadequate to meet the goals of "Healthy People 2000." Consequently, FDA felt it incumbent upon itself to "complement" Congress' work by embarking upon a more comprehensive regulatory program:

FDA believes that, if aggressively implemented and supported by both industry and public sector entities, comprehensive programs designed to discourage youthful tobacco consumption could reasonably achieve the "Healthy People 2000" goal.

Id.

In the end, FDA's decision to regulate tobacco products was tantamount to treating "Healthy People 2000" as independent or supplemental authorization to embark upon tobacco regulation. That is, since congressional action would not achieve the goals of that report, FDA decided it would achieve them by agency fiat. But

[f]ormulation of policy is a *legislature's* primary responsibility, entrusted to it by the electorate
"Without explicit action by law-makers, decisions of

great constitutional import and effect would be relegated by default to administrators who, under our system of government are not endowed with authority to decide them."

Robel, 389 U.S. at 276 (Brennan, J., concurring in the result) (emphasis added, citation omitted). FDA's decision to regulate tobacco to achieve the goals of "Healthy People 2000" is one that FDA simply did not have the authority to make.

The sheer number of comments received in response to FDA's Proposed Rule,² the contentiousness of the current litigation, and the bald fact that tobacco products are manifestly marketable to a profitable proportion of American citizens, attests to the fact that a sizeable segment of the United States population has a stake in national tobacco policy. FDA's perception that our nation's tobacco policy has failed to promote what is best for the American people's health may indicate that direct congressional legislation has been ineffective or inefficient in addressing problems related to the use of tobacco products. But the failure of Congress to establish or implement a forceful national policy is not a legal ground for the extra-democratic exercise of power being flexed here by FDA. Acquiescence to administrative action in this case would amount to sanctioning a system in which our government is made up of one branch--the executive--whose intentions may be unimpeachable, but whose practices are nonetheless unsuited to a democratic republic.

In *Federal Trade Commission v. Ruberoid Co.*, 343 U.S. 470 (1952), Justice Jackson, in dissent, exclaimed:

² The comments were so numerous that the Final Rule consumed 922 pages of the Federal Register, and the FDA addressed matters ranging far outside of its expertise, including the nondelegation doctrine, federal preemption doctrine, the First Amendment, and the Fifth Amendment's Takings Clause. 61 Fed. Reg. 44,396-45,318 (1996).

The rise of administrative bodies probably has been the most significant legal trend of the last century and perhaps more values today are affected by their decisions than by those of all the courts, review of administrative decisions apart. They also have begun to have important consequences on personal rights. They have become a veritable fourth branch of the Government, which has deranged our three-branch legal theories. . . .

Federal Trade Commission, 343 U.S. at 487. While Justice Jackson decried the rise of the administrative state, administrative agencies are a fact of modern life. And what keeps administrative agencies from devolving into Justice Jackson's distrusted "fourth branch" are the checks placed upon agency power by the actions of the three constitutionally sanctioned branches: agency power is limited by legislative delegations, executive discretion, and judicial review. In short, administrative agencies do not upset our three-branch system precisely because they can be maintained within the constitutional system of checks and balances.

But FDA's unprecedented foray into the area of tobacco regulation upsets this balance. FDA's decision amounts to one of *establishing* national tobacco policy, rather than merely applying it through a valid legislative delegation. The task of establishing national policy on a matter as politically and economically charged as tobacco is not one that can be assumed by an executive agency in isolation. Rather it is a task that properly belongs in Congress.

The principle that authority granted by the legislature must be limited by adequate standards serves two primary functions vital to preserving the separation of powers required by the Constitution. First, it insures that *the fundamental policy decisions in our society*

will be made not by an appointed official but by the body immediately responsible to the people.

Arizona v. California, 373 U.S. 546, 626 (1963) (Harlan, J., dissenting) (emphasis added).

When Congress enacted the Food, Drug and Cosmetic Act, it made laws, not legislators. See *Industrial Union*, 448 U.S. at 673 (Rehnquist, J., concurring in the judgment). National tobacco policy is of tremendous importance to many American citizens politically, economically, and personally. It cannot be credibly contended that Congress committed this policy to the jurisdiction of FDA in the absence of any language whatsoever specifying that authority. "It is the hard choices, and not the filling in of the blanks, which must be made by the elected representatives of the people." *Id.* at 687 (Rehnquist, J., concurring in the judgment). Because policy matters of this scale must be made by Congress, and may not be made by administrative agencies, this Court should affirm the decision of the Court below that FDA has no authority to regulate tobacco products.

II

IN ADOPTING REGULATIONS GOVERNING TOBACCO PRODUCTS, FDA HAS ACTED *ULTRA* *VIRE*S BY UNREASONABLY EXERCISING AUTHORITY BEYOND THE BOUNDS OF ITS LEGISLATED DELEGATION

FDA's recent change of position leading to its decision to exercise jurisdiction over tobacco products should not be given "controlling weight" under *Chevron*. Brief for the Petitioners at 17. The rationale announced in *Chevron*, though well-suited to the issue in that case, does not carry as much force in other contexts. As explained below, one of those contexts is in the area of determining agency jurisdiction.

The *Chevron* doctrine is not a blanket doctrine of deference to administrative agency determinations. Instead, its holding is rather specific. *Chevron* dealt with a regulation promulgated by the Environmental Protection Agency to implement the Clean Air Act Amendments of 1977. *Chevron*, 467 U.S. at 840-41. EPA was charged with establishing standards for a state permitting program to regulate "new or modified major stationary sources" of air pollution. *Id.* at 840. In implementing the Act, EPA adopted a regulation which defined "stationary source" to mean an entire plant, rather than each emitting device within a plant. *Id.* By defining "stationary source" in this manner, which was dubbed the "bubble" concept, an industrial facility could modify one or another of its emitting devices and, so long as the total plant's emissions remained below requisite levels, it would fall under the same permit. *Id.* The Natural Resources Defense Council challenged the EPA's regulation. *Id.*

In upholding EPA's regulation, this Court announced a test to determine the validity of agency regulations:

First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter, for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.

Id. at 842-43. Thus, this Court cast the analysis as one in which a court resolves two questions: (1) has Congress resolved the issue through its statute; and (2) is the agency's construction of the statute permissible. If the answer to the first is no and the second yes, then the Court must defer to the agency's determination.

There are problems with applying this test to FDA's tobacco regulation in the way FDA suggests. First, FDA jumps right to answering question two--that is, they argue that their interpretation is reasonable--without sufficiently resolving the first question: whether Congress has spoken to the question at issue. Second, even if the Food, Drug and Cosmetic Act could be understood to have left this matter to the agency's discretion, the doctrine of deference does not necessarily apply to an agency's interpretation of its own jurisdiction.

A. FDA's Reliance upon *Chevron* Is Misplaced, Because Congress Did Not Delegate the Authority to FDA to Regulate Tobacco Products in the Food, Drug and Cosmetic Act

Of course, Congress did not specifically state in the Food, Drug and Cosmetic Act that FDA did *not* have jurisdiction over tobacco products. However, the record is clear that, until 1996, this *lack* of congressional specificity had been consistently interpreted by FDA to preclude its jurisdiction over tobacco. Accordingly, Congress has consistently regulated tobacco directly, without reference to FDA. Thus, deference to FDA's new interpretation of its jurisdiction is not appropriate.

From 1914 until FDA's tobacco rule in 1996, FDA repeatedly and consistently maintained that it did not have jurisdiction over tobacco products. *Brown & Williamson*, 153 F.3d at 168. And even though the term "drug" has been part of FDA's jurisdictional mandate since 1906, and the term "device" has been part of the jurisdictional mandate since 1938, FDA "repeatedly informed Congress that cigarettes marketed

without therapeutic claims do not fit within the scope of the Act." *Id.* Indeed, FDA refused to exercise jurisdiction over cigarettes in 1977 partly on the basis that

"Congress, had the matter been considered, would not have intended cigarettes to be included as an article 'intended to affect the functions of the "body of man" or in any other definition of "drug."'"

Id. at 169 (citations omitted). FDA's new position contends these earlier pronouncements are irrelevant: congressional silence amounts to an agency license, rather than a limitation.

But, though Congress may have been silent in the Act, Congress was not silent as a general matter. Congress repeatedly considered delegating authority to FDA to regulate tobacco--and repeatedly rejected it. *See id.* at 170-73. Instead, Congress regulated tobacco products directly--even to the point of specifically addressing some of the same concerns that appear to have motivated FDA in this case. *Id.* at 175. Thus, this is not a case in which "congressional inaction demonstrates 'unawareness, preoccupation, or paralysis.'" *Brown & Williamson*, 153 F.3d at 170-71 (citation omitted).

Congress specifically addressed tobacco regulation in the Cigarette Labeling and Advertising Act, 15 U.S.C. § 1331, stating:

It is the policy of the Congress, and the purpose of this chapter, to establish a *comprehensive Federal program* to deal with cigarette labeling and advertising with respect to any relationship between smoking and health.

15 U.S.C. § 1331. Congress also enacted the Comprehensive Smokeless Tobacco Health Education Act, 15 U.S.C. § 4401, *et seq.*, to address health effects and labeling requirements for smokeless tobacco. These congressional actions specifically regulating tobacco products are relevant to the question of

FDA's authority to regulate tobacco products under its general authority over drugs and devices.

A basic rule of statutory construction to be applied to resolve a conflict between two different enactments each of whose literal terms cover a specific subject is that "where there is no clear intention otherwise, a specific statute will not be controlled or nullified by a general one"

Brown-Forman Distillers Corp. v. Mathews, 435 F. Supp. 5, 13 (W.D. Ky. 1976) (citing *Morton v. Mancari*, 417 U.S. 535, 550-51 (1974)) ("Where there is no clear intention otherwise, a specific statute will not be controlled or nullified by a general one, regardless of the priority of enactment.") Thus, even if FDA correctly concluded that tobacco products are drugs or devices within the general terms of the Food, Drug and Cosmetic Act, they could not be understood to override the terms of Congress' more specific tobacco legislation.

In *Brown-Forman Distillers*, a federal district court rejected the FDA's assertion of jurisdiction under circumstances remarkably similar to those presented here. In that case, FDA, for the first time in its history, promulgated regulations in 1975 governing alcoholic beverage labeling. *Brown-Forman Distillers*, 435 F. Supp. at 7. However, FDA's regulations conflicted with regulations promulgated by the Bureau of Alcohol, Tobacco and Firearms, which consistently had been exercising its authority over alcohol labeling according to specific legislation enacted in 1935. *Id.* at 7-8. *Brown-Forman Distillers* brought suit for declaratory and injunctive relief, asking the Court to determine whose regulations governed. *Id.* at 9. The Court found against FDA, despite its conclusion that the "plain language" of the Food, Drug and Cosmetic Act's definition of "food" gave FDA jurisdiction over alcoholic beverages. *Id.* at 12. The Court's reasoning as it applies to

alcoholic beverage labeling is equally well-suited to FDA's regulation of tobacco:

In so holding we specifically refuse to accept the defendants' contention that Congress' failure to exclude specifically the labeling of alcoholic beverages from the provisions of the 1938 Act . . . was a dispositive indication of Congress' intention to include labeling authority over alcoholic beverages within the jurisdiction of the FDA. Although such an explicit statement would have been simple for Congress to include within the Act, its failure to do so is not dispositive given the fact that (1) legislative history . . . demonstrates that Congress did not believe the 1938 legislation included labeling authority over alcoholic beverages; and, (2) three years prior to the 1938 Act Congress had previously passed legislation related directly to alcoholic beverages which included a specific and comprehensive section on labeling of such beverages To accept the defendants' argument we would have to believe that Congress intended to inflict upon the alcoholic beverage industry conflicting labeling requirements. We refuse to make such an assumption.

Id. at 16.

In the present case, the history of FDA's position and federal tobacco policy in general, demonstrate that the Food, Drug and Cosmetic Act's failure to *exclude* tobacco from FDA jurisdiction is not a significant indicator of congressional intent. In the face of FDA's consistent and repeated claims that it had no jurisdiction over tobacco, it would have been rather remarkable for Congress to go to the trouble of stating the fact explicitly, particularly when Congress had manifestly chosen to regulate tobacco directly. Congressional silence in the Food,

Drug and Cosmetic Act, under these circumstances, means that Congress did not recognize a need to exclude tobacco products from FDA's jurisdiction because it was generally understood that the Act did not give FDA jurisdiction over them.

B. Even If the Terms "Drug" or "Device" Within Food, Drug and Cosmetic Act Were Ambiguous, the *Chevron* Doctrine Does Not Necessarily Entitle FDA to Define the Limits of Its Own Jurisdiction

1. *Chevron* Does not Apply to Every Agency Determination

As explained above, *Chevron* dealt with a relatively narrow agency determination, specifically, whether the statutory term "stationary source" could reasonably be interpreted by EPA to include an entire plant for the purposes of establishing regulatory permit standards. But not all agency interpretations of statutes they are charged with administering have the same narrow policy implications that were at stake in *Chevron*. There, several factors militated in favor of a policy of deference. First, the best means by which to regulate emissions sources was a matter that EPA, given its experience and expertise, could resolve better than Congress, particularly for the purpose of establishing a workable and enforceable regulatory scheme. Deference is owed particularly where

"the statutory policy in the given situation has depended upon more than ordinary knowledge respecting the matters subjected to the agency regulations."

Chevron, 467 U.S. at 844 (citation omitted). Second, requiring judicial deference to the agency's determination in that context, rather than allowing the various state and federal courts to interpret statutory language anew, advanced the overall federal goal of establishing consistent national standards upon which individuals and states could justifiably rely. See, Kenneth Culp

Davis and Richard J. Pierce, Jr., *Administrative Law Treatise*, Vol. 1 § 3.4, at 116-18 (3rd ed. 1994). As the Court in *Chevron* explained,

In these cases, the Administrator's interpretation represents a reasonable accommodation of manifestly competing interests and is entitled to deference: the regulatory scheme is technical and complex, the agency considered the matter in a detailed and reasoned fashion, and the decision involves reconciling conflicting policies.

Chevron, 467 U.S. at 865. Here, these factors which made *Chevron*'s doctrine of deference compelling are absent. The question of whether tobacco is a "drug" or "device" is not a question on which FDA can bring some special knowledge not within the sphere of Congress' own expertise. Further, FDA has not reached its conclusion in a detailed or reasoned fashion, nor has its policy decision dispelled policy conflicts. Instead, FDA's decision has served to exacerbate such conflicts. See, e.g., *Brown-Forman Distillers*, 435 F. Supp. at 14.

Despite the cautionary language in *Chevron*, it is not always obvious under what circumstances *Chevron*'s deferential standard should apply. See, e.g., *INS v. Cardoza-Fonseca*, 480 U.S. 421 (1987); *Dole v. United Steelworkers of America*, 494 U.S. 26 (1990) (In both cases, justices disagreed as to the applicability of *Chevron* deference to an administrative agency determination.). Deference is most suited to those situations in which the agency's determinations relate to matters that fall within an agency's particular expertise or where statutory ambiguities unmistakably manifest Congress' intent that the agency resolve policy questions within a narrow set of parameters. It is inappropriate where deference would result in an inconsistent and unworkable federal regulatory scheme. Here, if substantial deference were given to FDA's determinations of its own jurisdiction, the result would be "delegation

running riot,"--Congress abdicating its responsibility to resolve an important question of national policy and the judiciary sanctioning a "roving commission." *A.L.A. Schechter Poultry Corporation v. United States*, 295 U.S. 495, 551, 553 (1935) (Cardozo, J., concurring).

[W]here, as here, the review is not of a question of fact, but of a judgment as to the proper balance to be struck between conflicting interests, "(t)he deference owed to an expert tribunal cannot be allowed to slip into a judicial inertia which results in the unauthorized assumption by an agency of major policy decisions properly made by Congress."

National Labor Relations Board v. Brown, 380 U.S. 278, 292 (1965) (citation omitted). "It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress." *Bowen v. Georgetown University Hospital*, 488 U.S. 204, 208 (1988). This Court has emphasized that "[a]n agency may not finally decide the limits of its statutory power. That is a judicial function." *Social Security Board v. Nierotko*, 327 U.S. 358, 369 (1946). Thus,

[t]he determination of the extent of authority given to a delegated agency by Congress is *not left for the decision of him in whom authority is vested*.

Addison v. Holly Hill Fruit Products, 322 U.S. 607, 616 (1944) (emphasis added).

The judicial policy of not deferring to agency determinations of their own jurisdiction is sound. Administrative agencies must operate "canalized within banks that keep it from overflowing," *A.L.A. Schechter Poultry*, 295 U.S. at 551 (Cardozo, J., concurring), and those "canals" are constructed by Congress, not the agency itself. If an agency were capable of reconfiguring the contours of its jurisdictional canals at will, the enabling legislation would be rendered meaningless--

congressional enactments would serve as nothing more than midwives to independent governing bodies. Thus, while it is appropriate to defer to agency determinations of matters which Congress has unequivocally placed into the hands of an administrative agency (as was the case in *Chevron*), the determination of an agency's jurisdictional limits must remain a judicial question, lest the agency "bootstrap itself into an area in which it has no jurisdiction by repeatedly violating its statutory mandate." *Federal Maritime Commission v. Seatrain Lines, Inc.*, 411 U.S. 726, 745 (1973).³

[T]he scope of the FDA's authority does not rest on its assertion of authority but on the actual jurisdiction conferred upon it by Congress through legislative enactment, as construed by the Courts.

Brown-Forman Distillers Corp., 435 F. Supp. at 17. Because, ultimately, the question is one of judicial, rather than agency, interpretation of statutes, *Chevron* deference does not apply. Instead, this Court's role is to examine whether Congress conferred authority on FDA to regulate tobacco, regardless of FDA's assertions. Given the history of FDA's administration of the Act and Congress' enactment of laws specifically regulating tobacco products, the implications of reading a power to regulate tobacco into FDA's relatively vague statutory mandate

³ *United States v. Riverside Bayview Homes, Inc.*, 474 U.S. 121, 123 (1985), is not contrary authority. That case was a challenge to an as-applied assertion of jurisdiction over wetlands adjacent to navigable waters. This Court found that whether the particular waters in question were "inseparably bound up with 'waters' of the United States" was a matter within the agencies' "technical expertise." *Riverside Bayview*, 474 U.S. at 134. But the Court specifically stated that its holding did *not* address *all* of the agencies' assertions of jurisdiction under the Act. *Id.* at 131 n.8. See *United States v. Wilson*, 133 F.3d 251 (4th Cir. 1997), and *National Mining Association v. United States Army Corps of Engineers*, 145 F.3d 1399 (cases holding that jurisdictional rules adopted by EPA and Corps under Clean Water Act were *ultra vires*).

to regulate "drugs" or "devices" would result in an unmanageable and inconsistent federal regulatory system in which congressional policies established under its tobacco-specific legislation could be undermined or contradicted by FDA policy. This is a result that the *Chevron* doctrine was specifically designed to discourage. This Court's "clear duty in such a situation is to reject the administrative interpretation of the statute." *Securities and Exchange Commission v. Sloan*, 436 U.S. 103, 119 (1978).

2. Even If the *Chevron* Doctrine Required This Court to Defer to an Agency's Determination of Its Own Jurisdiction, Deference Is Not Owed to an Agency's Change of Position Where the Change Is Unreasonable

One factor to be considered in giving weight to an administrative ruling is "the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control."

S.E.C. v. Sloan, 436 U.S. at 117-18 (citations omitted). FDA's current rule governing the sale and advertising of tobacco products lacks these factors which suggest judicial deference. In fact, administrative law principles favor FDA's prior position. In particular, the recent vintage of FDA's new jurisdictional determination renders its current arguments regarding interpretation of its statutory delegation unpersuasive.

As mentioned above, Congress gave FDA jurisdiction over "drugs" and "devices" in the Pure Food and Drugs Act of 1906 and the Food, Drug and Cosmetic Act of 1938. From 1914 until 1996, the FDA affirmatively denied jurisdiction over tobacco products. *Brown & Williamson*, 153 F.3d at 168. The Act's definition of "drug," which has remained relatively unchanged through the years, includes "articles (other than

food) *intended to affect* the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1)(C). The Act's definition of "device" includes a "contrivance . . . intended to affect the structure or any function of the body." 21 U.S.C. § 321(h)(3). As noted by the Court below, FDA derived its former stance partly from the belief that these terms, particularly given the phrase "intended to affect," did not include articles such as cigarettes so long as they were "marketed without health claims." *Brown & Williamson*, 153 F.3d at 169 (citation omitted). In addition, the agency concluded that jurisdiction over tobacco was inconsistent with congressional intent. *Id.* Now, however, FDA has changed its position. It claims that, in order for an article to be classified as a "drug" or "device" it is not necessary that the marketer make any specific health-related claims for the article. Brief for the Petitioners at 19. Instead, it is enough that the marketer "knows" that its product will have a particular effect: tobacco

manufacturers market their products with claims that they will provide "satisfaction," a "code-word" for the pharmacological effects of nicotine.

Id.

This startlingly recent change in the agency's position should not be countenanced by this Court. Legislative delegations are not unlimited grants of power that can be stretched and compressed at the whim of an agency or as the winds of political sensibilities shift. If any delegation was made by Congress to FDA to regulate tobacco products, that delegation had to have occurred in 1906 or 1938. It is rather a late date for FDA to suddenly discover that those earlier Congresses granted it extraordinarily broad powers that it has heretofore overlooked.

This is not to say that an agency is always obliged to adhere to one interpretation of a statute. This Court has acknowledged that

"[a]n administrative agency is not disqualified from changing its mind." . . . [But] "[a]n agency interpretation of a relevant provision which conflicts with the agency's earlier interpretation is 'entitled to considerably less deference' than a consistently held agency view."

Good Samaritan Hospital v. Shalala, 508 U.S. 402, 417 (1993) (citations omitted). An agency's change in position opens the door to a more expanded and skeptical inquiry by this Court and, in particular, this Court should *disfavor* changes which result in upsetting long-settled expectations:

It is a settled doctrine of this court that in case of ambiguity the judicial department will lean in favor of a construction given to a statute by the department charged with the execution of such statute, and, if such construction be acted upon for a number of years, will look with disfavor upon any sudden change.

United States v. Alabama G.S.R. Co., 142 U.S. 615, 621 (1892). Thus, what is entitled to deference here is not the agency's current interpretation of "drugs" and "devices," but FDA's *prior* construction of the Act, acted upon for a number of years, maintaining that these terms exclude tobacco products. The agency's former interpretation not only reflects the agency's contemporaneous construction of its enabling statute, it is a construction that the agency adhered to for 82 years. See *Alabama G.S.R. Co.*, 142 U.S. at 621; *Davis v. United States*, 495 U.S. 472, 484 (1990) ("[W]e give an agency's interpretations and practices considerable weight where they involve the contemporaneous construction of a statute and where they have been in long use.") See also *General Electric Co. v. Gilbert*, 429 U.S. 125, 142 (1976) (Court rejected agency interpretation where "[i]t is not a contemporaneous interpretation of Title VII,

since it was first promulgated eight years after the enactment of that Title.")

Further, the agency's prior interpretation was not simply a by-product of agency inaction or silence. On the contrary, the FDA repeatedly and specifically asserted that it lacked jurisdiction over tobacco products. *Brown & Williamson*, 153 F.3d at 168-70. What is more, this agency position was conveyed to Congress, *id.* at 170. As this Court has stated:

Although we are chary of attributing significance to Congress' failure to act, a refusal by Congress to overrule an agency's construction of legislation is at least some evidence of the reasonableness of that construction, particularly where the administrative construction has been brought to Congress' attention through legislation specifically designed to supplant it.

Riverside Bayview Homes, 474 U.S. at 137 (citations omitted). See also *Zuber v. Allen*, 396 U.S. 168, 192 (1969) (Agency interpretation "carries most weight when the administrators . . . directly made known their views to Congress in Committee hearings."). Congressional silence in the face of FDA's long-held and vocal position that it lacked authority over tobacco can be cited, with considerable justification, for the proposition that Congress acquiesced in FDA's prior assertions that it lacked authority to regulate tobacco.

Principles of administrative law do not grant FDA the freedom to interpret afresh the Food, Drug and Cosmetic Act as though Congress had enacted the law yesterday. Whatever may have been the merits of interpreting "drug" or "device" to include tobacco products in 1906 or 1938, the day is long past when the agency could have justified its current rule under ordinary principles of deference. As this Court recognized in *Flood v. Kuhn*, 407 U.S. 258 (1972), when it refused to apply anti-trust law to professional baseball despite its express holding

that professional baseball constituted interstate commerce, in circumstances such as this, the reasonable course is to adhere to precedent:

We continue to be loath, 50 years after Federal Baseball and almost two decades after Toolson, to overturn those cases judicially when Congress, by its positive inaction, has allowed those decisions to stand for so long and, far beyond mere inference and implication, has clearly evinced a desire not to disapprove them legislatively.

Accordingly, we adhere once again to *Federal Baseball* and *Toolson* and to their application to professional baseball. . . . If there is any inconsistency or illogic in all this, it is an inconsistency and illogic of long standing that is to be remedied by the Congress and not by this Court.

Flood, 407 U.S. at 283-84 (emphasis added). If the judiciary is so bound by precedent as to require it to refer the revision of longstanding policy to Congress, an executive agency such as FDA is no less so.

The modern administrative state could not long survive if agencies could upset long-settled constructions of law, merely because a problem appeared in need of a solution. FDA was not created to be a "roving commission to inquire into evils and upon discovery correct them." *A.L.A. Schechter Poultry*, 295 U.S. at 551 (Cardozo, J., concurring). Rather, its mandate is more limited and, at this time, it is confined to the jurisdictional "canals" that have long guided its statutory mission. *Id.* This Court should affirm the decision of the court below and hold that FDA lacks the authority to regulate tobacco products.

CONCLUSION

FDA's assertion of authority to regulate tobacco products on the bare claim that such products may be shoehorned into FDA's delegated authority to regulate "drugs" and "devices" is dubious. The agency's determination is diametrically opposed to the position it took in 1914, and adhered to until 1996, that these terms did not include tobacco products. Not only did FDA make its views on this point known to the public, it made them known to Congress. And Congress relied upon these assertions in formulating national tobacco policy. It implemented this policy through the enactment of tobacco-specific legislation--without delegating further authority to FDA to implement that legislation.

Under these circumstances, FDA's attempt to expand dramatically its power to dictate national social policy is not entitled to judicial deference. FDA is not free to expand its mandate in the absence of congressional action.

For the foregoing reasons, Amicus respectfully requests this Court to affirm the decision of the court below.

DATED: September, 1999.

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No. 98-1152

IN THE
Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, *et al.*,
Petitioner,

v.

BROWN AND WILLIAMSON TOBACCO CORP., *et al.*,
Respondent.

On Writ of Certiorari
to the United States Court of Appeals
for the Fourth Circuit

**BRIEF OF WASHINGTON LEGAL FOUNDATION
AND U.S. REPS. CASS BALLENGER AND
HOWARD COBLE AS *AMICI CURIAE*
IN SUPPORT OF RESPONDENTS**

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Date: September 10, 1999

QUESTION PRESENTED

In adopting the Federal Food, Drug, and Cosmetic Act, did Congress intend to authorize the Food and Drug Administration to regulate tobacco products, as they are customarily marketed (i.e., without reference to claims of health benefits), as "drugs" or "devices?"

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**IN THE
SUPREME COURT OF THE UNITED STATES**

No. 98-1152

FOOD AND DRUG ADMINISTRATION, *et al.*,
Petitioner,

v.

BROWN AND WILLIAMSON TOBACCO CORP., *et al.*,
Respondent.

**On Writ of Certiorari
to the United States Court of Appeals
for the Fourth Circuit**

**BRIEF OF WASHINGTON LEGAL FOUNDATION
AND U.S. REPS. CASS BALLENGER AND
HOWARD COBLE AS *AMICI CURIAE*
IN SUPPORT OF RESPONDENTS**

STATEMENT OF INTEREST

The Washington Legal Foundation (WLF) is a nonprofit public interest law and policy center with supporters in all 50 states.¹ WLF regularly appears before federal and state

¹ Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part and that no person or entity, other than WLF, contributed monetarily to the
(continued...)

courts to promote economic liberty, free enterprise principles, and a limited and accountable government. To that end, WLF has appeared before this and other federal courts in cases in which federal administrative agencies have exceeded legal bounds in their regulation of the business community. See, e.g., *American Trucking Association v. U.S. Environmental Protection Agency*, 175 F.3d 1027 (D.C. Cir. 1999)(reh. pending). In *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), WLF successfully argued that Food and Drug Administration (FDA) efforts to restrict dissemination of truthful information about off-label uses of FDA-approved drugs and medical devices violate the First Amendment. WLF also participated in this matter as an *amicus curiae* when it was before the district court and the court of appeals.

Congressmen Cass Ballenger and Howard Coble are Members of the U.S. House of Representatives from North Carolina. They believe that it should be left up to Congress to decide whether, and to what extent, tobacco products should be regulated by FDA.

Amici are not simply concerned that FDA, in reaching out to exercise jurisdiction over tobacco products, has exceeded the bounds of its statutory authority. *Amici* are also concerned that FDA has justified its decision to exercise jurisdiction by interpreting its enabling statute in a manner that gives FDA unfettered discretion to regulate virtually any consumer product. Federal statutes interpreted in so

¹(...continued)
preparation and submission of this brief.

broad a manner raise troubling constitutional issues regarding the delegation of legislative power.

Amici submit this brief in support of Respondents with the written consent of all parties. The written consents are on file with the Clerk of the Court.

STATEMENT OF THE CASE

In the interests of judicial economy, WLF hereby incorporates by reference the Statement contained in the brief of Respondent R.J. Reynolds Tobacco Co.

In brief, in August 1996, the Food and Drug Administration (FDA) issued a final rule that sought to restrict the advertising and promotion of tobacco products as well as their sale and distribution. 61 Fed. Reg. 44,396 (1996). FDA had not previously claimed authority to regulate tobacco products as they are "customarily marketed" (i.e., without reference to claims of health benefits).² FDA claimed such authority based on its findings that tobacco products fall within the definitions of "drug[s]" and

² FDA has in the past exercised jurisdiction over tobacco products whose manufacturers marketed them on the basis of explicit health claims. See, *United States v. 354 Bulk Cartons Trim Reducing Cigarettes*, 178 F. Supp. 847 (D.N.J. 1959)(cigarettes marketed as effective in combating obesity); *United States v. 40 Cartons, More or Less, Containing Fairfax Cigarettes*, 113 F. Supp. 336 (D.N.J. 1953)(cigarettes advertised as effective in preventing respiratory and other diseases). However, FDA is not now asserting jurisdiction based on any allegations that health claims are being made for tobacco products, and the courts below viewed this case solely as a challenge to FDA's authority to regulate tobacco products as "customarily marketed." See, e.g., Pet. App. 14a, 19a.

"device[s]" under the Federal Food, Drug, and Cosmetics Act (Act), 21 U.S.C. § 301 *et seq.*

The Act defines a "drug" as including "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1)(C). The Act defines "device" as including an object:

[I]ntended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

21 U.S.C. § 321(h). FDA concluded that tobacco products qualify as both drugs and devices; FDA said that they are "combination products consisting of nicotine, a drug that causes addiction and other significant pharmacological effects on the human body, and device components that deliver nicotine to the body." 61 Fed. Reg. at 44,649-650.

Key to FDA's conclusion was its determination that tobacco products are "intended" to affect the structure or function of the human body. While acknowledging that tobacco manufacturers have not sought to market their products based on any health claims, FDA based its "intent" determination on three assertions. First, FDA asserted that it is foreseeable to manufacturers that consumers will use tobacco products in order to sustain a nicotine addiction and to experience nicotine's mood-altering and appetite suppressant effects. 61 Fed. Reg. at 44,701-739. Second,

FDA asserted that those uses are the predominant reason that people smoke; it asserted that non-pharmacological reasons for smoking are secondary. *Id.* at 44,807-846. Third, FDA asserted that manufacturers "have in mind" that consumers will use their products for their pharmacological effects; FDA based that assertion on evidence that manufacturers were aware of nicotine's effects and took steps to ensure that nicotine levels that exist naturally in tobacco were not reduced significantly during the manufacturing process. *Id.* at 44,847-097.

FDA had on numerous prior occasions concluded that it lacked jurisdiction under the Act to regulate tobacco products as customarily marketed, based primarily on a determination that such products are not "intended" to affect the structure or any function of the body in the absence of health claims directed to consumers. *See, e.g.*, Letter from FDA Commissioner Kennedy to Action on Smoking and Health (ASH) (Dec. 5, 1977), J.A. 44-49 ("The interpretation of the Act by FDA consistently has been that cigarettes are not drugs unless health claims are made by vendors."). FDA stated that it was entitled to change its mind regarding the proper interpretation of the Act's "intent" requirement and, furthermore, that the evidence upon which it based its intent determination was unavailable to FDA until relatively recently.

Having determined that tobacco products qualify as both drugs and devices, FDA asserted the right to regulate them under the device provisions of the Act. Pet. App. 13a. Pursuant to those provisions, it imposed numerous restrictions on sales and advertising of tobacco products. 61 Fed. Reg. at 44,616-618.

FDA summarily dismissed objections that its rationale for regulating tobacco products as drugs and devices applied with equal force to a broad range of consumer products not currently subject to FDA regulation. Without regard to whether such products (including, *e.g.*, guns and other weapons) are intended to affect the structure or any function of the body, FDA distinguished such products on the ground that they do not bring about the same level of pharmacological effects on the body as is produced by tobacco products. *Id.* at 44,682-685.

Respondents filed suit in federal district court, challenging FDA's actions on numerous grounds. On August 14, 1998, the U.S. Court of Appeals for the Fourth Circuit issued a decision striking down the FDA regulations on the ground that FDA lacks jurisdiction to regulate tobacco products — reversing the district court's decision on that issue. Pet. App. 1a-54a. The appeals court said that tobacco products could be found to fall within the Act's definition of drugs or devices only by applying “[a] mechanical reading of only the definitions provisions” of the Act. *Id.* at 19a. The appeals court held that an examination of the entire FDA regulatory scheme created under the Act, FDA's historical position on tobacco regulation, congressional response to that position, and tobacco-specific legislation adopted by Congress all indicate that Congress never intended to grant jurisdiction to FDA to regulate tobacco products. *Id.* at 20a-53a.

The Court granted FDA's petition for a writ of certiorari on April 26, 1999.

SUMMARY OF ARGUMENT

Amici agree with Respondents that the language and history of the Act, as well as the entire history of congressional regulation of tobacco products, indicate that Congress has never granted FDA authority to regulate tobacco products. *Amici* believe that FDA's interpretation of the Act is untenable for an additional reason: as interpreted by FDA, the Act constitutes an unconstitutional delegation of legislative power. Under FDA's interpretation, FDA would be free to regulate a broad range of heretofore unregulated consumer products, unshackled by any restrictions on its authority other than FDA's views regarding what best promotes public health. Moreover, the Act (as interpreted by FDA) allows the agency standardless discretion to impose whatever level of controls on a product it deems appropriate, without regard to whether those controls render the product safe for human use. Such wholesale delegation of legislative powers to an executive branch agency — without the provision of any intelligible principle by which FDA is to guide its conduct — would violate the Constitution's prohibition against such delegations. *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928). Congress should not be presumed to have legislated in such an unconstitutional manner; accordingly, FDA's newly minted interpretation of the Act should be rejected. *Industrial Union Dep't, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 646 (1980) (plurality) (“A construction of the statute that avoids [an] open-ended grant [of legislative power to an administrative agency] should certainly be favored.”).

FDA insists that tobacco products are "intended" to affect the structure/function of the body, despite its acknowledgment that manufacturers have never conveyed such an intent to consumers, and that (in the appeals court's words) "no court has ever found that a product is 'intended for use' or 'intended to affect' within the meaning of the Act absent manufacturer claims as to that product's use." Pet. App. 19a. Applying its newly enlarged definition of "intent," FDA based its "intent" determination with respect to tobacco products on three findings: (1) the foreseeability of consumer use of tobacco products in a manner designed to affect structure/function; (2) the predominance of such uses over uses in a manner not designed to affect structure/function; and (3) tobacco manufacturers "have in mind" that consumers will engage in such uses. But thousands of consumer products not now regulated by FDA and which FDA has shown no interest in regulating — e.g., guns, coffee makers — qualify as "drugs" or "devices" under FDA's new definition of "intent." When it applies that new definition, FDA can articulate no intelligible principle that explains its decision to regulate tobacco products but not the thousands of other products that meet FDA's "intent" threshold. In the absence of such an intelligible principle, FDA has unbridled authority to regulate consumer products as "drugs" or "devices" based solely on its views of public health needs. In contrast, the definition of "intent" employed before 1996 — that a manufacturer does not "intend" its product to affect the structure/function of the body unless the manufacturer conveys that intent to consumers in some way — provided clear congressional guidance regarding the limits of FDA jurisdiction.

FDA's decision to restrict tobacco sales and marketing without imposing a total ban is based on a similarly novel interpretation of its legislative authority to regulate drugs and devices. Numerous provisions of the Act indicate that FDA is to prohibit the distribution of drugs/devices unless FDA can assure that the products are safe and effective for their intended uses. *See, e.g.*, 21 U.S.C. §§ 355(c)(1)(A), 360e(d)(1)(A)(I). Yet, FDA now asserts that such provisions should be interpreted as granting it the discretion to regulate tobacco products as drugs and devices without banning them altogether, despite FDA's admission that none of its proposed restrictions on sales and marketing would render them safe or effective for any intended use. Thus freed of that formerly recognized restraint on its regulatory authority, FDA can point to no "intelligible principle" to guide its decision-making with respect to the extent of controls it will impose on the distribution of drugs and devices. Congress should not be assumed to have granted such standardless regulatory authority to FDA, which would amount to an unconstitutional delegation of legislative authority.

ARGUMENT

I. The Nondelegation Doctrine Imposes Constitutional Limits on Congress's Power To Delegate Its Authority to Representatives of the Executive Branch

Article I of the Constitution assigns all legislative powers within the federal government to Congress, and this Court has stood firmly behind the principle that Congress may not assign those powers to others. *See, e.g., Field v. Clark*, 143 U.S. 649, 692 (1892) ("That Congress cannot delegate legislative power to the president is a principle

universally recognized as vital to the integrity and maintenance of the system of government ordained by the Constitution."'). As John Locke -- whose opinions are credited with shaping the views of many of the Founders -- wrote more than 300 years ago:

The power of the legislative, being derived from the people by a positive voluntary grant and institution, can be no other, than what the positive grant conveyed, which being only to make laws, and not to make legislators, the legislative can have no power to transfer their authority of making laws, and place it in other hands.

J. Locke, *Second Treatise of Civil Government, in the Tradition of Freedom*, ¶ 141, at 244 (M. Meyer ed 1957)(quoted in *Industrial Union*, 448 U.S. at 472-73 (Rehnquist, J., concurring in the judgment)).

The prohibition against delegation of legislative power does not mean, of course, that only Congress may write rules that govern national affairs. Indeed, if Congress were prohibited from delegating to others the power to fill in the details of general laws adopted by Congress and to respond to contingencies whose precise details could never be anticipated, "the exertion of legislative power [w]ould become a futility." *Sunshine Anthracite Coal Co. v. United States*, 310 U.S. 381, 398 (1940). Thus, the Court's delegation doctrine "jurisprudence has been driven by a practical understanding that in our increasingly complex society, replete with ever changing and more technical problems, Congress simply cannot do its job without an ability to delegate power under broad and explicit directives." *Mistretta v. United States*, 488 U.S. 12 (1989).

But while Congress is permitted to seek the assistance of Executive Branch officials by granting them a considerable degree of discretion regarding how laws are to be carried out, there are constitutional limits on the extent of that discretion. A federal law is an unconstitutional delegation of legislative power if it fails "to lay down . . . an intelligible principle to which the person or body authorized to [exercise the delegated authority] is directed to conform." *J.W. Hampton*, 488 U.S. at 409. *J.W. Hampton's* "intelligible principle" test has been followed by the Court in numerous subsequent cases raising nondelegation doctrine issues, most recently in *Touby v. United States*, 500 U.S. 160, 165 (1991).

On at least two occasions, the Court has struck down federal laws on non-delegation doctrine grounds, in each case citing the "intelligible principle" test. *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935); *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935). In more recent years when the Court has invoked the nondelegation doctrine, it has done so to justify "giving narrow constructions to statutory delegations that might otherwise be thought to be unconstitutional." *Mistretta*, 488 U.S. at 373 n.7. See, *Industrial Union*, 448 U.S. at 646 (plurality)(narrow construction given to provisions of the Occupational Safety and Health Act of 1970, 29 U.S.C. § 651 *et seq.*, in order to avoid a construction giving rise to a potentially unconstitutional delegation of legislative powers); *Cable Television Ass'n v. United States*, 415 U.S. 336, 342 (1974). See also, *American Trucking Associations, Inc. v. United States Environmental Protection Agency*, 175 F.3d 1027, 1034-40 (D.C. Cir. 1999) (EPA's construction of §§ 108-09 of the Clean Air Act, 42 U.S.C. §§ 7408-09, is invalid because those statutory provisions would fail to

provide EPA with any "intelligible principle" to guide its rulemaking and thus would amount to an unconstitutional delegation of legislative powers if construed in the manner proposed by EPA)(reh. pending).

II. FDA's Unprecedented Interpretation of What Constitutes "Intent" To Affect the Structure/Function of the Body Results in a Regulatory Regime Lacking Any "Intelligible Principle," To Guide FDA's Determination of Which Products It Is Authorized To Regulate

In support of its decision to assert jurisdiction over tobacco products, FDA has proposed a novel interpretation of the Act's definitions of "drug" and "device." The result of that interpretation is that thousands of additional consumer products now fall within those definitions; of those additional products, FDA has disclaimed any desire to assert jurisdiction other than in the case of tobacco products. Yet, FDA has been unable to point to any "intelligible principle" in the Act that would justify differentiating between tobacco products and those other products; under FDA's interpretation of the Act, FDA is left to its unfettered discretion to determine whether such products will be regulated as drugs/devices. Accordingly, under this Court's nondelegation doctrine jurisprudence, FDA's interpretation of the Act must be rejected.

FDA has statutory authority to regulate as "drug[s]" or "device[s]" only those products that are "intended" to affect the structure or any function of the body. 21 U.S.C. §§ 321(g)(1)(C) and 321(h)(3). Prior to 1996, FDA interpreted those statutes as meaning that a product was not a "drug" or a "device" if the manufacturer made no health

claims regarding the product. That bright-line methodology -- limiting FDA jurisdiction to products marketed with medical claims -- ensured that FDA would have a principled basis for determining which products were subject to regulation. It also provided manufacturers with express guidance as to when their products would not be subject to FDA regulation: their products would not be subject to FDA regulation if they neither directly nor indirectly made any claims that their products would promote health by "affect[ing] the structure or any function of the body." Pursuant to that interpretation, FDA informed ASH in its 1977 letter that cigarettes are not "drugs" unless health claims are made by vendors. J.A. 44-49.

Now that it has decided to assert jurisdiction over tobacco products, FDA has revised its interpretation of "intended." FDA now contends that the requisite "intent" can be established based on other evidence, even if a manufacturer makes no claims regarding its product's effect on structure/function. In this case, FDA based its "intent" determination with respect to tobacco products on three findings: (1) it is foreseeable that consumers will use tobacco products in a manner designed to affect structure/function; (2) such uses predominate over uses of tobacco products in a manner not designed to affect structure/function (*e.g.*, smoking because one enjoys the taste); and (3) tobacco manufacturers "have in mind" that consumers will engage in such uses.

The difficulty with FDA's revised interpretation of "intended" is that it engulfs thousands of consumer products that have never previously been thought to be subject to FDA regulation -- because the manufacturers have never included in their marketing any claims that their products are

to be used "to affect the structure or any function of the body." Nonetheless, although consumer products are rarely marketed in that manner, what FDA says about tobacco products -- that manufacturers foresee that consumers will use their products in a manner that "affect[s] the structure or function of the body" -- can be said about a myriad of items.

An insulated glove keeps the wearer's hands warm so that he or she can stay outside longer -- thus "affect[ing]" "function" (raising hand temperature and increasing ability to "function" out of doors). Similarly, shirts, pants, and coats "affect the structure or function" of the body by trapping warmth, and possibly moisture, to much the same effect as insulated gloves. A catcher's mitt protects the "structure" of the wearer's hands from being injured by a fastball; an air conditioner affects body "function" by helping to regulate body temperature, and improving "function[ing]" on a hot summer day; a hammock affects body "function" by affecting blood flow. A ladder elevates the climber, enabling him or her to "function" more effectively. None of these products has been subject to FDA regulation because health claims generally are not made in connection with their marketing.³ But manufacturers are well aware that consumers routinely use these products in order to affect body structure/function, and they are highly unlikely to take steps to discourage such uses. Accordingly, such products fall squarely within the definition of "device" adopted by FDA in connection with its tobacco proceedings.

³ When such products are marketed in the health-care context, they have been subjected to FDA regulation as "device[s]." For example, air conditioners produced for use in hospitals and which are marketed based on their health benefits for hospital patients have been regulated by FDA. FDA Br. 21.

FDA has responded to criticisms that its new definitions of "drug" and "device" will engulf thousands of additional consumer products, by insisting that such products are distinct from tobacco and thus that FDA will not assert jurisdiction over them. Tellingly, FDA has *not* contended that such products are not "drug[s]" or "device[s]" as FDA has defined those terms in connection with its tobacco regulations. Rather, it has merely highlighted distinctions between such products and tobacco products that are not germane to FDA's new definitions.

For example, a number of commenters asserted that guns and ammunition would qualify as "device[s]" under FDA's new scheme, because gun manufacturers are well aware that an overwhelming number of consumers use guns "to affect the structure or any function of the body of man or other animals," 21 U.S.C. § 321(h)(3), and many guns are designed precisely to enhance their ability to have such effects. FDA responded that guns and other weapons are distinguishable from tobacco products because "tobacco products achieve their effects on the structure and function of the body through nicotine's pharmacological effects," while guns have no similar pharmacological effects. 61 Fed. Reg. at 44,684-685. But while that response may serve to explain why guns should not be deemed a "drug," it does nothing to explain why guns should not be deemed a "device"; indeed, most medical devices do *not* have any pharmacological effects. FDA simply failed to respond directly to the charge that tobacco products are indistinguishable from thousands of other consumer products on the key issue of "intent" to affect structure/function.

A number of other commentators suggested that caffeine-containing and caffeine-related products -- such as

coffee and coffee makers -- should be regulated as drugs or devices under FDA's new definition of "intent." FDA responded that those products are distinguishable because "food" is explicitly excepted from the definition of "drug" (21 U.S.C. § 321(g)(1)(C)), and because "the effects of these caffeine-containing products on the structure and function of the body are significantly less than those for nicotine. . . . For instance, unlike nicotine, caffeine is not recognized at this time as an addictive drug." 61 Fed. Reg. at 44,683-684. But the Act's definition of "device" does not contain a similar exemption for food, so there is no reason that coffee makers and coffee mugs (as "instrument[s]" that deliver caffeine to the body) could not be deemed "device[s]." Moreover, the relative effects of caffeine and nicotine on structure/function of the body have no bearing on whether coffee is "intended" to have such effects, as that word is now defined by FDA. There is little doubt that most consumers drink coffee to experience the pharmacological effects of the caffeine contained therein, and that manufacturers of coffee makers and mugs are well aware of that motivation. Thus, coffee makers and mugs meet FDA's new definition of "device[s]" just as assuredly as do tobacco products; the only difference is that FDA has chosen to regulate only the latter.

To be sure, FDA has provided numerous explanations regarding why it deems tobacco products to fall within its new definition of drugs and devices and why it deems numerous other, seemingly-similar products not to be covered. For example, other products may not be "associated with harms to health" (61 Fed. Reg. at 44,681), or may not achieve their effects "through pharmacological means." *Id.* at 44,678. But these are distinctions that derive solely from FDA itself; FDA can point to no language in the Act that

sets forth an "intelligible principle" from which FDA derived these distinctions. If tobacco products are "devic[e]s" under FDA's newly adopted definition of that term, then so are thousands of other products that also meet that definition.

The only possible construction of the Act that could save FDA's decision to regulate tobacco products but not to regulate those other products is a construction that grants FDA unfettered discretion in deciding whether to regulate a product deemed to be a "drug" or "device." But, as noted above, the nondelegation doctrine prohibits Congress from granting such unfettered discretion to executive branch agencies. Accordingly, FDA's interpretation of the "intent" component of the Act's drug/device definitions must be rejected because it would raise serious concerns regarding the constitutionality of the Act as so construed. *Industrial Union*, 448 U.S. at 646.

In the debate over unconstitutional delegations of legislative power, it is well established that "no statute can be entirely precise, and that some judgments, even some judgments involving policy considerations, must be left to the officers executing the law." *Mistretta*, 488 U.S. at 415 (Scalia, J., dissenting). Chief Justice John Marshall explained that while wholesale delegation of legislative powers is impermissible, the necessities of administration require that administrators be permitted to "fill up the details" with respect to matters "of less interest" so long as they are acting pursuant to "general provisions" of law set forth by Congress. *Wayman v. Southard*, 10 Wheat. (23 U.S.) 1, 41 (1825). Because Congress cannot possibly anticipate all events that may unfold following its adoption of legislation, it has no practical choice but to authorize an

administrator carrying out the legislation to make some policy decisions in order to deal with contingencies as they arise. *Field v. Clark*, 143 U.S. at 691.

But the practicality-based arguments in favor of permitting policy judgments to be made by members of the Executive Branch are at their weakest when, as here, the policy consequences are of such national importance and have been the subject of intense public focus. When Congress adopted the Act in 1938, it was well aware of tobacco products, and claims that those products had adverse health consequences. As the record in this case attests, Congress and the nation have focused repeatedly on whether and to what extent to regulate the sale and advertising of tobacco products. This is not a case in which "the inherent necessities" of running a government require that decisions regarding regulation of tobacco products be made by administrators. *Mistretta*, 488 U.S. at 372 (quoting *J.W. Hampton*, 276 U.S. at 406). Congress is quite capable of making the decision regarding whether tobacco products should be regulated by FDA.

Moreover, that decision in large measure boils down to a trade-off between, on the one hand, promoting public health and, on the other hand, preserving personal autonomy and avoiding disruption of the national economy. Decisions of that type are quintessentially legislative in nature and may not be delegated by Congress to others. *Industrial Union*, 448 U.S. at 685 (Rehnquist, J., concurring in the judgment) (the nondelegation doctrine "ensures to the extent consistent with orderly governmental administration that important choices of social policy are made by Congress, the branch of the government most responsive to the popular will."). FDA's interpretation of the Act is tenable only if the Act is

construed as a grant to FDA to decide in its unfettered discretion whether tobacco products should be regulated as drugs/devices. Because such a construction raises serious constitutional concerns under the nondelegation doctrine, FDA's interpretation of the Act must be rejected.

III. FDA Lacks Any "Intelligible Principle" To Guide Its Imposition of Regulations That Amount to a Less-Than-Total Ban on the Sale of Tobacco Products

Having determined that tobacco products are "drug[s]" and "device[s]" within the meaning of the Act, FDA has stopped short of imposing a total ban on the sale and distribution of such products -- even though FDA readily concedes that it is unaware of any use for which tobacco products are both safe and effective. Rather, FDA has chosen to impose restrictions on distribution and advertising that stop well short of a total ban. FDA's brief fails to cite any statutory provision that allows it to impose the limited restrictions that it has proposed; rather, FDA justifies its restrictions as necessary to maximize public health. FDA Br. 33. But in the absence of any "intelligible principle" in the Act to guide FDA restrictions on drugs/devices it has not deemed safe, any interpretation of the Act that would permit FDA to impose such restrictions would amount to an unconstitutional delegation of legislative powers to FDA. Accordingly, under the nondelegation doctrine, FDA's interpretation of the Act must be rejected.

As the court of appeals pointed out, numerous provisions of the Act require FDA to focus on whether drugs/devices are safe and effective for their intended uses. Pet. App. 20a-30a. For example, the device provision upon which FDA relies in order to regulate tobacco products, 21

U.S.C. § 360j(e), permits FDA to restrict the sale, distribution, or use of a medical device "if, because of its potentiality for harmful effect or the collateral measures necessary for its use, the Secretary determines that *there cannot otherwise be reasonable assurance for its safety and effectiveness*." (Emphasis added.) In other words, the sole basis for FDA imposition of restrictions under § 360j(e) is to provide "reasonable assurance" that the device is safe and effective. Accordingly, § 360j(e) provides no statutory support for the specific restrictions FDA has imposed on tobacco products because FDA does not claim that its restrictions would provide any kind of assurances that tobacco products would be safe and effective for some intended use.

FDA justifies its decision to impose restrictions that amount to less than a total ban, on its conclusion that harmful health consequences that would arise from a total ban would be worse than the health consequences of permitting tobacco sales to continue. FDA Br. 33-34. But nothing in the Act provides any "intelligible principle" to FDA suggesting how to engage in such balancing processes, or even that it is permitted to do so at all.⁴ FDA is left to assert that its balancing process "best comports with the public health purposes of the Act" (FDA Br. 33) -- which is tantamount to a claim that FDA has been given a roving

⁴ FDA's half-hearted citation to 21 U.S.C. § 360c(a)(2)(C) (FDA Br. 33) is misplaced. That provision requires FDA to make safety and effectiveness determinations based on "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." That provision cannot be read as permitting the adverse consequences of a ban to be counted as a "probable benefit to health" that would arise from the continued legal use of tobacco products.

commission to protect "public health" as it sees fit. Because FDA's interpretation of the Act as an open-ended delegation to FDA to take whatever steps it views as necessary to promote public health raises serious constitutional concerns under the nondelegation doctrine, that interpretation must be rejected.

FDA now appears ready to accept the possibility that its proposed restrictions are impermissible. In that event, FDA argues, it is prepared to go ahead and impose a total ban on sales on the ground that no level of restrictions can assure that tobacco products are safe and effective for an intended use. *Id.* at 34-37. FDA argues that invalidation of its proposed restrictions "would not affect the reasonableness of FDA's conclusion that tobacco products are drugs and devices within the meaning of the Act." *Id.* at 34. *Amici* strongly disagree. FDA concedes that its decision to impose only limited restrictions on tobacco sales was prompted by a recognition that a total ban would have a negative impact on public health. Yet, assuming that the Act requires FDA to ban all sales of drugs and devices not shown to be safe and effective, FDA's assertion of jurisdiction over tobacco products will require it to take steps that all agree will harm public health. That is a strong indication that Congress never intended to give FDA jurisdiction over tobacco products. *See*, Pet. App. 52a.

CONCLUSION

Amici curiae Washington Legal Foundation, *et al.*, respectfully request that the judgment of the Court of Appeals be affirmed.

Respectfully submitted,

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**On Writ of Certiorari to the
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**BRIEF OF AMICUS CURIAE
PRODUCT LIABILITY ADVISORY COUNCIL, INC.
IN SUPPORT OF RESPONDENTS**

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QUESTION PRESENTED

Whether the Food and Drug Administration's claim of jurisdiction to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act is entitled to deference under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

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INTEREST OF THE *AMICUS CURIAE*

• *Amicus curiae* Product Liability Advisory Council, Inc. ("PLAC") is a non-profit corporation whose membership consists of 123 major corporations engaged in a wide range of business activities in federally-regulated industries, including activities regulated by the Food and Drug Administration ("FDA") pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*¹ In the course of their business activities, PLAC's members are subject to numerous agency actions for which deference is claimed under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

The FDA's argument before this Court rests on an extraordinarily expansive view of *Chevron* that would require judicial deference for virtually every agency action. PLAC therefore has a substantial interest in the outcome of this case and believes that the Court would be materially aided by an in-depth analysis of the *Chevron* doctrine and its applicability to the FDA's claim of regulatory authority over tobacco.

SUMMARY OF ARGUMENT

This Court's decision in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), requires judicial deference to an agency's actions where Congress has delegated authority to the agency to interpret and enforce a statute. But this rule is subject to a key limitation: no deference is warranted where Congress has *not* delegated authority to an agency in a particular area. Before applying *Chevron* deference, therefore, a court must determine whether Congress intended to permit the agency to act in a given field. This review serves the vital purpose of ensuring that Congress, rather than the agency, makes the

¹ Pursuant to Supreme Court Rule 37, letters from the parties consenting to the filing of this brief have been filed with the Clerk of the Court. This brief was funded entirely by PLAC and was written entirely by its counsel.

major policy decisions, in order to further the political accountability necessary for a well-functioning administrative state.

The FDA's plea for *Chevron* deference to its jurisdictional claim over tobacco products cannot be reconciled with this fundamental limitation on the doctrine. The agency's assertion that Congress intended it to have regulatory authority over tobacco is based on isolated fragments of statutory text, read in a vacuum. It glosses over, or simply ignores, the overwhelming evidence to the contrary, all of which is relevant at the first step of the *Chevron* analysis. And it justifies its actions with a cramped and unsupported reading of *Chevron* that would mandate deference for virtually all agency actions. In sum, the government seeks to use *Chevron* — a doctrine that protects an agency's gap-filling authority where Congress has not spoken to an interstitial issue — to annex regulatory authority over an entire industry in a manner that raises political, economic, and social issues of enormous consequence. *Chevron* cannot be stretched so far.

The FDA's invocation of *Chevron* deference ignores two other essential limits on the doctrine's applicability. First, deference may not be appropriate where an agency is interpreting the scope of its own jurisdiction, rather than acting within its settled authority. Here, the FDA's jurisdictional claim rests on no special agency expertise, reflects an effort to expand its own power, and depends on the agency's interpretation of statutes that it has not been delegated authority to enforce. Second, deference may not be warranted for an agency position that is flatly at odds with a longstanding and contemporaneous construction of its statute. Here, the FDA's newly-minted position is based on an unexplained changed interpretation of congressional intent and infringes unduly on substantial reliance interests. Under these circumstances, it is unreasonable to assume that Congress intended the courts to defer to the FDA.

ARGUMENT

I. THE FDA IS NOT ENTITLED TO *CHEVRON* DEFERENCE BECAUSE CONGRESS DID NOT INTEND TO DELEGATE TO IT THE AUTHORITY TO REGULATE TOBACCO PRODUCTS

In *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, this Court set out a two-step analysis for reviewing an "agency's construction of the statute which it administers." 467 U.S. at 842. At step one, a court must determine "whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842-843. If Congress's intent is not clear, then the court must determine "whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843.

Judicial deference to an agency's statutory interpretation "reflects a sensitivity to the proper roles of the political and judicial branches." *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 696 (1991). But *Chevron* is not intended to give an agency *carte blanche* to decide when and how to regulate. *Chevron* is based on the premise that an agency is entitled to deference where Congress has delegated to it interpretive authority; "[f]rom this congressional delegation derives the [agency]'s entitlement to judicial deference." *Id.* at 698; see also *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649 (1990) ("A precondition to deference under *Chevron* is a congressional delegation of administrative authority."); *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988).

In ascertaining the scope of an agency's delegated power, a court may not lightly presume that Congress intended to grant major policymaking authority. "An implied delegation of a law-declaring function is especially likely where * * * the question is interstitial, involves the everyday administra-

tion of the statute, implicates no special judicial expertise, and is unlikely to affect broad areas of the law.” *St. Luke’s Hosp. v. Secretary of Health & Human Servs.*, 810 F.2d 325, 331 (1st Cir. 1987) (Breyer, J.). Conversely, the larger the question at stake, and the more significant its impact, the less likely it is that Congress intended to authorize the agency to decide it. See *MCI Telecomms. Corp. v. AT&T Co.*, 512 U.S. 218, 231-232 (1994); *Mayburg v. Secretary of Health & Human Servs.*, 740 F.2d 100, 106 (1st Cir. 1984) (Breyer, J.).

Meaningful review of congressional intent at *Chevron’s* step one is essential to ensure against “‘unauthorized assumption by an agency of major policy decisions.’” *Bureau of Alcohol, Tobacco & Firearms v. FLRA*, 464 U.S. 89, 97 (1983) (quoting *American Ship Bldg. Co. v. NLRB*, 380 U.S. 300, 318 (1965)); see also *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 214 n.33 (1976) (refusing to accept agency interpretation that would “rais[e] serious policy questions not yet addressed by Congress”). *Chevron* deference is intended to further political accountability in regulatory policymaking, not to countenance an agency’s unwarranted usurpation of legislative power. By asking whether Congress intended to permit an agency to exercise authority in a given area before giving deference to the agency’s decision, a court applying *Chevron’s* step one “ensures to the extent consistent with orderly governmental administration that important choices of social policy are made by Congress, the branch of our Government most responsive to the popular will * * *.” *Industrial Union Dep’t, AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 685 (1980) (Rehnquist, J., concurring).

As this analysis demonstrates, *Chevron’s* step one — the determination whether Congress has given an “express” or “implicit” “delegation of authority to the agency to elucidate a specific provision of the statute by regulation,” 467 U.S. at 843-844 — serves a critically important *judicial* function. It comes as no surprise, therefore, that in assessing congressio-

nal intent under *Chevron’s* step one, this Court gives no deference to the agency’s position. See *Pauley*, 501 U.S. at 696-698; *Dole v. United Steelworkers of Am.*, 494 U.S. 26, 32-44 (1990); *Chevron*, 467 U.S. at 845; see also *Federal Election Comm’n v. Democratic Senatorial Campaign Comm.*, 454 U.S. 27, 31-32 (1981).

A. The Text, Structure, And Legislative History Of The FDCA And Tobacco-Related Statutes Show That Congress Intended That The FDA Would Not Have Regulatory Authority Over Tobacco Products

Under *Chevron’s* step one, it is clear that Congress did not intend to give the FDA the power to regulate tobacco products.² Because the terms of the FDCA, when interpreted in light of the Act’s structure and legislative history, as well as the structure and history of tobacco-related statutes, reveal Congress’s contrary intent, the FDA’s interpretation of the Act is not entitled to deference under *Chevron*.

We will not burden the Court with a lengthy recitation of the powerful evidence showing that Congress did not intend to delegate to the FDA the authority to regulate cigarettes and other tobacco products. Under the FDCA, the agency is authorized to regulate only those products whose “intended use,” as determined by the manufacturer’s or distributor’s claims, is to affect a body’s structure or function. See Brief of Respondent R.J. Reynolds Tobacco Co. at 11-21; Brief of Respondent Brown & Williamson Tobacco Corp. at 6-27 (discussing meaning of “intended use”). Furthermore, the statute’s delegation of authority to regulate “drugs” and “devices” is limited to products with a real or claimed

² By referring to the regulation of tobacco or tobacco products, PLAC intends to encompass only tobacco or tobacco products as customarily marketed. We do not dispute that the FDA would have authority to regulate tobacco products (or any other products) for which therapeutic claims are made.

medical or therapeutic effect on the body. See Brief of Respondents United States Tobacco Co., *et al.*, at 9-20 (discussing meaning of "drug" and "device"). Clearly, tobacco products as commonly marketed do not fall within the terms of the statute.³

The legislative history of the FDCA and the tobacco-related statutes supports this reading of the plain language. Congress has been regulating the packing, labeling, marketing, and production of tobacco for nearly 100 years. See, e.g., Pub. L. No. 57-237, 32 Stat. 714 (1902); Pub. L. No. 61-5, 36 Stat. 108-111 (1909); Pub. L. No. 73-483, 48 Stat. 1275 (1934); Pub. L. No. 74-314, 49 Stat. 731 (1935); Pub. L. No. 75-430, 52 Stat. 31 (1938). Nothing in the FDCA, enacted in 1938, suggests an intent to include tobacco — at that time (as now) a significant and discrete industry, governed by tobacco-specific federal statutes — within its reach. See Brief of Respondents Philip Morris Incorporated, *et al.*, at 6-11 (discussing evidence of congressional intent).

³ Although the government argues that the "plain language" of the FDCA supports its exercise of jurisdiction, the FDA has conceded that under its literal interpretation it would also have regulatory jurisdiction over such products as thermal pajamas, exercise equipment and home air conditioners (see Appellee and Reply Brief for FDA in the Fourth Circuit at 20), a result that cannot be squared with the intended scope of the FDCA. Furthermore, the FDA's interpretation of the "plain language" would require a ban on the off-label use of many drugs, a consequence that would have serious adverse health effects. See *Brown & Williamson Br.* at 27-31. Thus, even if the "plain language" of the statute were otherwise clear, these absurd consequences would warrant an examination of the legislative history of the FDCA and other evidence of congressional intent. See *Green v. Bock Laundry Mach. Co.*, 490 U.S. 504, 509-510 (1989); *id.* at 527 (Scalia, J., concurring); Breyer, *On the Uses of Legislative History in Interpreting Statutes*, 65 S. CAL. L. REV. 845, 849 (1992) (use of legislative history to prevent absurd results "seems uncontroversial").

Beginning shortly after 1938, the year that the FDCA was enacted, the FDA consistently represented that it did not have regulatory jurisdiction over tobacco. See *Philip Morris Br.* at 10-14, 18-19, 22-31 (describing repeated statements by FDA officials). To the extent that the FDA's interpretation of the FDCA provides evidence of its intended scope, the agency's interpretation contemporaneous with the statute's enactment is far stronger evidence than the agency's unexplained, opposite interpretation decades later. See *Aluminum Co. of Am. v. Central Lincoln Peoples' Util. Dist.*, 467 U.S. 380, 390 (1984); *Zenith Radio Corp. v. United States*, 437 U.S. 443, 450 (1978); Scalia, *Judicial Deference to Administrative Interpretations of Law*, 1989 DUKE L.J. 511, 518.

The FDA's lack of regulatory authority over tobacco has been confirmed in the decades since 1938. Congress considered, and failed to enact, numerous bills that would have given the FDA the power to regulate tobacco products, manifesting Congress's understanding that the FDA did not already possess such authority under the FDCA. See *Philip Morris Br.* at 11-21, 28-31, 33-35 (listing failed legislative efforts). Congressional committee reports and members of Congress repeatedly stated that the FDA lacked regulatory authority over tobacco and that any further regulation of the industry must be accomplished by congressional action. See *ibid.* Agency officials acknowledged the correctness of this understanding as well, time and again disavowing any regulatory jurisdiction over tobacco. See *id.* at 12-14, 18-19, 22-31.

Finally, in reliance on this understanding, Congress has enacted numerous laws directly regulating tobacco or delegating enforcement authority to agencies other than the FDA or to the States. See Pub. L. No. 89-92, 79 Stat. 282 (1965); Pub. L. No. 91-222, 84 Stat. 87 (1970); Pub. L. No. 98-24, 97 Stat. 175, 178 (1983); Pub. L. No. 98-474, 98 Stat. 2200 (1984); Pub. L. No. 99-252, 100 Stat. 30 (1986); Pub. L. No. 102-321, 106 Stat. 323 (1992). This statutory ratification

of the FDA's longstanding position is compelling evidence that the agency's disclaimer of jurisdiction was correct. See, e.g., *CFTC v. Schor*, 478 U.S. 833, 846 (1986) (where "Congress has not just kept its silence by refusing to overturn the administrative construction, but has ratified it with positive legislation, we cannot but deem that construction virtually conclusive") (quotation marks omitted). Moreover, the substantive terms of these statutes are in serious conflict with the FDA's claim of regulatory authority under the FDCA. See *Philip Morris Br.* at 35-43.⁴

Under *Chevron's* step one, all of this evidence is relevant in determining whether Congress has spoken to the FDA's regulatory authority over tobacco. See *Chevron*, 467 U.S. at 843 n.9 ("traditional tools of statutory construction" and other evidence of legislative intent considered at step one); see also, e.g., *MCI Telecomms. Corp.*, 512 U.S. at 231-234 (considering general purpose of statute and later-enacted legislation); *United States Nat'l Bank v. Independent Ins. Agents of Am., Inc.*, 508 U.S. 439, 455 (1993) (considering entire law, and its object and policy); *Dole*, 494 U.S. at 35-43 (considering legislative history and "language, structure, and purpose" of statute); *Chemical Mfrs. Ass'n v. Natural Resources Defense Council, Inc.*, 470 U.S. 116, 125-133 (1985) (considering statutory text, history, structure, and purpose).

And when examined, this evidence plainly shows that Congress has *not* authorized, and did *not* intend, the FDA to exercise regulatory authority over tobacco. Under step one of *Chevron*, therefore, the FDA's contrary conclusion (even if it might be deemed plausible) is not entitled to deference. See *Chevron*, 467 U.S. at 842-843; see also, e.g., *Pittston Coal Group v. Sebben*, 488 U.S. 105, 113-115 (1988); *id.* at

⁴ The FDA's tobacco regulations also cannot be reconciled with the operative terms of the FDCA, which would require the FDA to ban tobacco — a result directly at odds with congressional intent. See *R.J. Reynolds Br.* at 27-30; page 20, *infra*.

124 (Stevens, J., dissenting); *Sullivan v. Zebley*, 493 U.S. 521, 536-537 (1990); *id.* at 543 (White, J., dissenting).

B. The Government's Arguments for Deference Are Based On A Misapplication Of *Chevron's* Step One

The most notable aspect of the government's analysis of *Chevron* is its near-total disregard of *Chevron's* step one: the government makes little effort to show that the statutory text, statutory framework, legislative history, or other relevant sources demonstrate that Congress intended to delegate to the FDA the authority to decide whether tobacco products should be regulated under the FDCA. Instead, the government asserts that the case must be resolved at *Chevron's* step two, and that the agency's assessment of its authority to regulate tobacco must be given deference, because "it simply is not possible to conclude that Congress specifically addressed the question and clearly denied FDA authority to regulate tobacco products." FDA Pet. Reply 3; accord FDA Br.16-17 (arguing that *Chevron* step two deference applies because Congress has not unambiguously expressed an intent about whether the FDA has authority to regulate tobacco as a "drug" or "device").

The government's elision of *Chevron's* step one is especially curious given its arguments in the courts below. The agency told both the district court and the Fourth Circuit that the case could be decided at step one of the *Chevron* analysis because, "[b]y its plain terms, the [FDCA] encompasses these tobacco products as drugs and devices." FDA Appellee Br. 12; see also FDA Defendants' Brief in Opposition to Plaintiffs' Motions for Summary Judgment at 23 ("[T]his court need not proceed past step one of the *Chevron* analysis."). It is difficult to understand why, if Congress's intent was crystal-clear in the lower courts, it has suddenly become obscured. The government has provided no explanation for this striking about-face.

The FDA's cursory treatment of *Chevron's* step one is also incompatible with *Chevron* itself. The government's approach to *Chevron* would turn nearly every statutory construction case into a step two reasonableness test, which the agency would almost invariably win. This simplistic analysis would render *Chevron's* step one virtually meaningless and would undermine fatally its utility as a guard against undue delegation of major policymaking authority and agency usurpation of legislative power. *Chevron* does not mandate such abdication of the judicial role.

The government invokes deference because "Congress has conferred on FDA the authority to administer the [FDCA]." FDA Br. 16. But agencies always purport to act pursuant to statutes that they have been authorized to administer. Nonetheless, an agency's enforcement authority "only permits the [agency] to police within the boundaries of the Act; it does not permit the [agency] to expand its jurisdiction beyond the boundaries established by Congress." *Board of Govs. of Fed. Res. Sys. v. Dimension Fin. Corp.*, 474 U.S. 361, 373-374 & n.6 (1986). To grant deference whenever an agency claims to act under its enabling statute would ignore the fundamental limitation that no deference is warranted where congressional intent is clear. In any event, the government's argument is factually incorrect: the question of the FDA's jurisdiction to regulate tobacco not only turns on the meaning of the FDCA, but also implicates the meaning of other statutes that the FDA has *not* been directed by Congress to administer. See pages 7-8, *supra*.

In a related vein, the government asserts that *Chevron* deference applies because the FDA was delegated the authority to determine whether products are "drugs" or "devices" under the Act. See FDA Br. 17-18 & n.3; see also FDA Pet. 18. This, too, begs the question: in enacting the FDCA, did Congress intend the FDA to have authority to regulate tobacco products? The fact that the FDCA contains broad definitions of "drug" and "device" does not answer that

predicate question, nor does it mean that Congress intended to give the FDA limitless authority to regulate anything that might fall within a possible interpretation of the statutory definitions. A statute is not ambiguous simply because Congress has not, in so many words, answered a question on its face. *Chevron's* step one requires an assessment of *all* probative evidence of congressional intent to delegate regulatory authority to the agency; as we have already explained, the evidence shows that Congress did *not* intend to authorize the FDA to regulate tobacco, notwithstanding its enactment of broad definitions of "drug" and "device." See pages 5-9, *supra*.⁵

The government also suggests that deference is proper because, in enacting the definitions of "drug" and "device," Congress did not "clearly den[y] FDA authority to regulate tobacco products." See FDA Pet. Reply 3; see also FDA Br. 16-17. But we have already explained that a statute is not

⁵ The FDA's argument appears to be based on the premise that if Congress had known in 1938 what the FDA claims to know now, it would have included tobacco products within the FDCA. But if the FDA's lack of authority to regulate tobacco has become "an anachronism," "it is the responsibility of Congress" — not the agency — to change course. *Maislin Indus., U.S., Inc. v. Primary Steel, Inc.*, 497 U.S. 116, 136 (1990); see also *MCI Telecomms. Corp.*, 512 U.S. at 234 ("our estimations, and the Commission's estimations, of desirable policy cannot alter the meaning of the federal Communications Act of 1934"). As this Court has recognized, although agencies must be able to change position to meet new conditions arising *within* the scope of their authority, an expansion of the scope of agency authority based on changed circumstances must come from Congress itself. See *Board of Govs.*, 474 U.S. at 365, 373-375.

The FDA's "changed circumstances" argument also ignores the fact that Congress has already considered the possibility of "changed circumstances" with respect to tobacco regulation and has set out statutorily-mandated procedures pursuant to which agencies can bring new information about tobacco to Congress with proposals for legislative response. See 15 U.S.C. §§ 1337, 1341(a), (c), 4407.

ambiguous merely because it does not explicitly address a particular issue or explicitly withhold authority from the agency. Under the government's approach, an agency would be entitled to deference in every case unless Congress expressly prohibited the regulation of a particular product, industry, or field. Yet the more overreaching or unintended the agency's claim of regulatory power, the less likely it is that Congress would have expressly withheld authority — notwithstanding that it is precisely in these circumstances that Congress would not intend the agency to act. See Breyer, *Judicial Review of Questions of Law and Policy*, 38 ADMIN. L. REV. 363, 370-371 (Fall 1986). The government's approach would place an intolerable burden on Congress, which would be required to enact elaborate and heavily detailed definitional sections or risk the possibility that an agency's extravagant jurisdictional claim would be given judicial deference. And the government's position would impose an almost insurmountable barrier on private litigants challenging agency action as outside the scope of the agency's authority. Notably, the government offers no authority for its argument. See *Ethyl Corp. v. EPA*, 51 F.3d 1053, 1060 (D.C. Cir. 1995) ("To suggest * * * that *Chevron* step two is implicated any time a statute does not expressly *negate* the existence of a claimed administrative power * * * is both flatly unfaithful to the principles of administrative law * * * and refuted by precedent.").

Finally, the government contends that it is simply irrelevant that Congress repeatedly rejected bills designed to give the FDA the power it now seeks and instead enacted laws directly regulating tobacco and delegating enforcement authorities to other agencies. See FDA Br. 42-44. But Congress's conduct demonstrates not only its acquiescence in, but also its ratification of, the FDA's frequently-stated position that it lacked regulatory authority over tobacco. See pages 7-8, *infra*. The government's disregard of this highly

probative evidence cannot be squared with *Chevron*'s step one requirement to faithfully determine the intent of Congress.

II. THE FDA'S CLAIM THAT IT IS ENTITLED TO DEFERENCE IGNORES OTHER FUNDAMENTAL LIMITATIONS ON THE *CHEVRON* DOCTRINE

In addition to ignoring the clear intent of Congress, the FDA's argument for deference is based on a disregard of fundamental limits on the *Chevron* doctrine consistently recognized and applied by this Court. Two crucial features in this case — that the agency is interpreting the scope of its own jurisdiction, and that the agency's position breaks sharply and inexplicably with its longstanding interpretation of the FDCA — support a more skeptical and searching review of the agency's actions.

A. The FDA's Claim Of Jurisdiction Over An Entirely New Regulatory Area Does Not Involve Specialized Agency Expertise And Depends On The Interpretation Of Statutes The Agency Has Not Been Authorized To Enforce

As this Court has long recognized, an agency's determination of the scope of its own jurisdiction is not automatically entitled to judicial deference. See, e.g., *Federal Maritime Comm'n v. Seatrain Lines, Inc.*, 411 U.S. 726, 745 (1973) (agency may not invoke discretion to "bootstrap itself into an area in which it has no jurisdiction"); *SEC v. Sloan*, 436 U.S. 103, 119 (1978) (same).

There are sound reasons for this principle. To begin with, an agency's claim of new regulatory authority "may be motivated by designs for agency aggrandizement rather than by a disinterested assessment of statutory authority and appropriate policy." Merrill, *Judicial Deference to Executive Precedent*, 101 YALE L.J. 969, 1024 (1992); accord Sunstein,

Constitutionalism After the New Deal, 101 HARV. L. REV. 421, 467 (1987) ("foxes should not guard henhouses").

Furthermore, the premise of *Chevron* is that Congress intends an agency to apply its technical and policymaking expertise within an area of delegated authority. See *Chevron*, 467 U.S. at 843-844. But as this case shows, an agency's interpretation of jurisdictional boundaries often does not implicate agency expertise. To the contrary, a jurisdictional limit may reflect a determination by Congress of the outer limit of the agency's abilities, "a direct refutation of the agency's expertise." Gossett, Comment, *Chevron, Take Two: Deference to Revised Agency Interpretations of Statutes*, 64 U. CHI. L. REV. 681, 694 (1997). Cf. *Leedom v. Kyne*, 358 U.S. 184, 190 (1958) ("This Court cannot lightly infer that Congress does not intend judicial protection of rights it confers against agency action taken in excess of delegated powers.").

Accordingly, it is unreasonable to assume that Congress deemed each piece of enabling legislation to be "an open book to which the agency could add pages and change the plot line." Gellhorn & Verkuil, *Controlling Chevron-Based Delegations*, 20 CARDOZO L. REV. 989, 1011 (1999). It is especially unlikely that Congress intended to allow an agency to define the limits of its own jurisdiction when the agency seeks to regulate in an entirely new and unprecedented area, as the FDA seeks to do in this case. *Id.* at 1012. "The more significant the question and the greater the impact that expansion of the agency's jurisdiction is likely to have, the greater the likelihood that Congress did not intend implicitly to delegate that determination to an agency." *Id.* at 1008; see also *Industrial Union Dep't.*, 448 U.S. at 645 (plurality op.) (refusing to infer that Congress intended to delegate to OSHA "unprecedented power over American industry"); *id.* at 669 (Powell, J., concurring) ("It is simply unreasonable to believe that Congress intended OSHA to pursue the desirable goal of risk-free workplaces to the extent that the economic viability

of particular industries — or significant segments thereof — is threatened.").

The case for denying deference is particularly strong where, as here, an agency's jurisdictional claim involves not just the statute it has been authorized to administer, but also statutes granting interpretive and enforcement authority to *other* agencies. The FDA has no special insight in interpreting these other statutes, or in reconciling conflicting policy goals to accomplish those statutes' purposes. See *Adams Fruit*, 494 U.S. at 649-650 (refusing to defer to agency's interpretation of statute that it was not authorized to enforce). Cf. *Bureau of Alcohol, Tobacco & Firearms*, 464 U.S. at 98 n.8. Indeed, judicial deference in these circumstances might lead to conflicting, and irreconcilable, statutory interpretations by different agencies. See *Martin v. Occupational Safety & Health Review Comm'n*, 499 U.S. 144, 152 (1991) (resolving "'jurisdictional' dispute" between two agencies with divided responsibility for enforcement of the same statute); see generally Weaver, *Deference to Regulatory Interpretations: Inter-Agency Conflicts*, 43 ALA. L. REV. 35 (1991).

Thus, even if congressional intent were not so clear, the FDA's bold assertion of the jurisdiction to regulate (and even ban) tobacco — which Congress has characterized as an industry whose activities "cut across the whole spectrum of commercial and social life in the United States," and one in which "Congress, if anyone, must make policy" (see H.R. REP. NO. 91-289, at 5 (1969)) — should be greeted skeptically. This is hardly a case in which the agency has merely "fill[ed] a gap" or defined a statutory term in a way that comports with "the legislature's revealed design." FDA Br. 17 (quoting *Chevron*, 467 U.S. at 844). Rather, as even FDA Commissioner Kessler acknowledged in 1994, regulation of tobacco products raises "societal issues of great complexity and magnitude." See *Letter from FDA Commissioner Kessler to Scott Ballin* 3 (Feb. 25, 1994), reprinted in *Regulation of Tobacco Products (Part 1), Hearings Before the Subcomm. on*

Health and the Environment of the House Comm. of Energy and Commerce, 103rd Cong. 25 (1994). In these circumstances, it is simply unreasonable to conclude that Congress intended the courts to defer to the FDA's claim of jurisdiction over tobacco.

To be sure, a few members of this Court have suggested that agencies should be given deference on jurisdictional matters because it is difficult to distinguish between jurisdictional and non-jurisdictional claims and because virtually every agency action can be characterized as "jurisdictional." *Mississippi Power & Light Co. v. Mississippi*, 487 U.S. 354, 380-383 (1988) (Scalia, J., concurring); *Dole*, 494 U.S. at 53-54 (White, J., dissenting). While this rationale may have merit in some contexts, it is plainly inapplicable here. The FDA's claim of authority to regulate tobacco — a distinct, multi-billion-dollar industry, subject to industry- and product-specific statutes enforced by other agencies, not heretofore considered to be within the FDA's regulatory power — is indisputably jurisdictional. See Sunstein, *Law and Administration After Chevron*, 90 COLUM. L. REV. 2071, 2097, 2100-2101 (1990). The difficulty in identifying purely "jurisdictional" claims is not implicated in this case.

The government erroneously relies on *CFTC v. Schor*, 473 U.S. at 844-845, and *NLRB v. City Disposal Systems, Inc.*, 456 U.S. 822, 830 n.7 (1984), for the contention that the FDA's jurisdictional claim warrants *Chevron* deference. See FDA Br. 17 n.3. In *Schor*, Congress had expressly delegated authority to the CFTC to determine the scope of its own jurisdiction over counterclaims. See 478 U.S. at 846. Because Congress's intent on the jurisdictional issue was clear, *Chevron* deference was inapplicable. *Id.* at 845-847. *City Disposal* — and the other cases collected in Justice Scalia's concurrence in *Mississippi Power & Light* (FDA Br. 17 n.3) — involved an agency's determination about *how* it would regulate a product or activity over which it undoubt-

edly possessed regulatory authority.⁶ None of these cases involved an agency's attempt to exercise power in an entirely new and unprecedented area based on its interpretation of statutes that it was not delegated authority to enforce. And none of them supports the radical proposition that an agency's assertion of jurisdiction is always entitled to deference — no matter how purely jurisdictional, no matter how extreme the consequences of the power grab, no matter how dependent on interpretation of statutes enforced and administered by other agencies, and no matter how attenuated from the agency's traditional regulatory sphere.

B. The FDA's Newly-Asserted Jurisdictional Claim Is Not Based On A Reasoned Analysis And Ignores Legitimate Reliance Interests

The FDA's assertion of jurisdiction to regulate tobacco products also is not entitled to judicial deference because it conflicts with views that the agency has long maintained on the identical issue of statutory construction. As this Court recently recognized, an agency interpretation that "conflicts with the agency's earlier interpretation is entitled to consider-

⁶ In *City Disposal*, for example, the National Labor Relations Board determined that assertion of a collective bargaining right constituted "concerted activity" within the meaning of the National Labor Relations Act, a statute that Congress intended to be interpreted by the Board to protect employees' concerted efforts to enforce collective bargaining rights. *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 700 (1984), involved the Federal Communications Commission's regulation of cable television, over which Congress intended the FCC to have regulatory authority. See *United States v. Southwestern Cable Co.*, 392 U.S. 157, 168 (1968). *CBS, Inc. v. FCC*, 453 U.S. 367, 382 (1981), and *Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 379-381 (1969), involved FCC requirements that television stations provide responsive broadcasts or broadcast access. Both the FCC's general jurisdiction over television stations, and its specific authority to regulate broadcasts and mandate access, were beyond doubt. See *CBS*, 453 U.S. at 379-382, 386; *Red Lion*, 395 U.S. at 379-380.

ably less deference than a consistently held agency view." *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 417 (1993) (internal quotation marks omitted); see also *INS v. Cardoza-Fonseca*, 480 U.S. 421, 446 n.30 (1987); *Pauley*, 501 U.S. at 698. Although "an initial agency interpretation is not instantly carved in stone," *Chevron*, 467 U.S. at 863, there are limits on an agency's ability to break sharply with past practices.⁷ The agency must justify its changed interpretation with a reasoned analysis, see, e.g., *Rust v. Sullivan*, 500 U.S. 173, 186-187 (1991); and the new position must not infringe legitimate reliance interests, see *Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. 735 (1996). The government has not satisfied either of these requirements.

The FDA's claim of authority over tobacco products relies on a change in its position on two crucial issues. To begin with, the FDA has rejected its longstanding interpretation of the requirement that a drug or device be "intended to affect the structure or any function of the body of man" in order to fall within the scope of the FDCA. See 21 U.S.C. §§ 321(g)(1)(C), 321(h)(3). Traditionally, the FDA took the position that the "intended use" of a drug or device was *determined by a manufacturer's express or implicit claims*. See *Brown & Williamson Br.* at 18-27. Now, for the first time, the FDA asserts that a product's "intended use" may be determined by the effects sought by consumers and subjectively intended by manufacturers, even if no express or implied claims are made. This change in position was essential to the FDA's claim of regulatory authority over tobacco, for which neither express nor implicit therapeutic claims have been made.

⁷ Here, of course, the FDA's interpretation of the FDCA was not "instantly carved in stone," but instead was etched there over decades, as the agency time and again reiterated that it had no jurisdiction over tobacco products.

The FDA's new interpretation of "intended use" has staggering implications for the manufacture and sale of pharmaceutical products, and in particular for off-label uses of such products. See *Brown & Williamson Br.* at 27-31. Expanding the definition of "intended use" in this way also renders the pre-market approval process for new drugs and devices and for generic drugs and follow-on devices much more difficult, expensive, and time-consuming. See *id.* at 31-34. And even if the FDA chooses not to ban the off-label use of a drug or device — a choice it appears to lack the discretion to make — its new interpretation of "intended use" would provide a predicate for state law tort suits and challenges to FDA approvals and clearances by competitors, consumer groups, and others. See *id.* at 34-35. Nowhere has the agency addressed the enormous implications of its changed position.

The FDA's only explanation for embracing its new interpretation of "intended use" is that it has new evidence that nicotine is addictive; that most users of tobacco products seek to satisfy a nicotine addiction and to obtain nicotine's physiological effects; and that manufacturers know that their products are used in this way and "deliberately engineer[] their products to deliver active doses of nicotine." *FDA Br.* 38-39. But as the respondents have demonstrated, the FDA was aware of evidence of each of these factors for years or even decades, and yet continued to disclaim authority to regulate tobacco. See *Philip Morris Br.* at 12-15, 24-27. In short, the FDA's claim of "changed circumstances" both is demonstrably false as a historical matter and falls woefully short of the "reasoned analysis" required for such a sharp break with a prior position — particularly when its new position would have such extraordinary practical consequences and would lead to such a quantum expansion of agency jurisdiction. See, e.g., *Smiley*, 517 U.S. at 742; see also *Georgetown Univ. Hosp.*, 488 U.S. at 212-213; *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 355-

356 (1989); *Motor Vehicles Mfrs. Ass'n of United States, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983).

The FDA's new position also represents a sharp break with its considered views on a second issue. The FDA has long explained that it lacked jurisdiction to regulate tobacco because, if the FDCA were applicable, it would be required to ban tobacco from the market. See *Cigarette Labeling and Advertising Hearings Before the House Comm. on Interstate and Foreign Commerce*, 88th Cong. 13, 18 (1964) (letter from Secretary of Health, Education and Welfare); *Hearings Before the Consumer Subcomm. of the Senate Comm. on Commerce on S. 1454*, 92d Cong. 239, 242 (1972) (testimony of FDA Commissioner); *id.* at 245 (testimony of FDA Asst. General Counsel for Foods, Drugs & Product Safety Division). According to the FDA, this result was untenable because banning tobacco "would be inconsistent with the clear congressional intent." *Hearings Before the Consumer Subcomm. of the Senate Comm. on Commerce on S. 1454*, 92d Cong. 242; accord *id.* at 245.

The FDA now claims, however, for the first time, that its assertion of jurisdiction over tobacco is *not* dependent on whether it would be required by the FDCA to ban tobacco. In the FDA's own words, a conclusion "that the Act, as presently written, requires tobacco products to be banned * * * would in no way undermine FDA's conclusion that tobacco products * * * [are] subject to regulation under the Act." FDA Br. 14; accord *id.* at 34 ("Even assuming the regulatory provisions of the Act would require tobacco products to be banned, however, that would not affect the reasonableness of FDA's conclusion that tobacco products are drugs and devices within the meaning of the Act.").

Because the FDA cannot act in conflict with Congress's intent, see *Chevron*, 467 U.S. at 842-843, the agency's current position must be premised on its belief that Congress did not in fact intend tobacco products to remain legal. Yet

the FDA has offered *no* explanation whatsoever for its total about-face on the critical question whether Congress was willing to countenance a ban on cigarettes. Indeed, the government's brief barely mentions the issue — and does so only to assert that Congress's intent about whether tobacco sales should be prohibited is not "dispositive" and that, if unhappy with a ban, Congress could overturn the result by passing *new* legislation. See FDA Br. at 35-36 & n.7. Accordingly, the FDA's new jurisdictional argument, which is premised on this unexplained shift, warrants no deference. See *Smiley*, 517 U.S. at 742; *NLRB v. United Food & Commercial Workers Union*, 484 U.S. 112, 124 (1987); *Cardoza-Fonseca*, 480 U.S. at 446.

Finally, the agency's new claim of jurisdiction over tobacco must fail because its prior disclaimer of authority has given rise to substantial reliance interests. See, e.g., *Smiley*, 517 U.S. at 742; *Zenith Radio Corp.*, 437 U.S. at 457-458. Both federal and state legislators have enacted laws premised on the FDA's lack of regulatory authority in this area. See *R.J. Reynolds Br.* at 36-47 (discussing federal and state tobacco-related laws). That legislation was the result of a political compromise: the labeling, advertising and sale of tobacco products would be subject to stringent federal and state regulation; in return, tobacco would remain on the market. And the political compromise was based on the fundamental premise that the FDA lacked regulatory authority over tobacco. Cf. *Scalia, Judicial Deference*, 1989 DUKE L.J. at 517 (purpose of *Chevron* deference is to give Congress a background presumption against which to legislate). The FDA cannot suddenly change its mind and thereby make nonsense of the congressionally chosen enforcement scheme. See, e.g., *International B'hd of Teamsters v. Daniel*, 439 U.S. 551, 568-570 (1979); *Morton v. Ruiz*, 415 U.S. 199, 236-237 (1974).

CONCLUSION

The FDA's claim of jurisdiction to regulate tobacco products under the FDCA should not be given deference under *Chevron*, and the judgment of the court of appeals should be affirmed.

Respectfully submitted.

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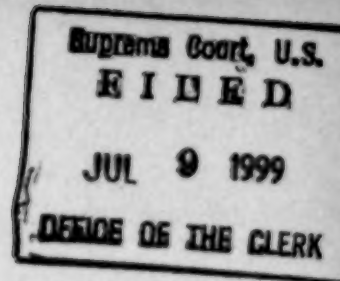
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SEPTEMBER 1999

(24)

No. 98-1152

IN THE



Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION,
Petitioner,

v.

BROWN & WILLIAMSON TOBACCO CORP., ET AL.,
Respondents.

On Writ of Certiorari to the
United States Court of Appeals
for the Fourth Circuit

**BRIEF OF
AMERICAN COLLEGE OF CHEST PHYSICIANS
AS AMICUS CURIAE IN SUPPORT OF PETITIONER**

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BRIEF OF AMERICAN COLLEGE OF CHEST PHYSICIANS AS AMICUS CURIAE IN SUPPORT OF PETITIONER

The American College of Chest Physicians, pursuant to Supreme Court Rule 37, submits this brief *amicus curiae* in support of Petitioner, the Food and Drug Administration ("FDA"), seeking reversal of the United States Court of Appeals for the Fourth Circuit's ruling that the Food, Drug, and Cosmetic Act ("FDCA") does not authorize the FDA to regulate the sale and promotion of tobacco products. The American College of Chest Physicians has received the consent of all parties to file this brief as *amicus curiae*, and letters of consent have been filed concurrently with this brief.¹

¹ Pursuant to Rule 37.6 of this Court, the Amicus states that no party had any role in writing this brief and that no one other than the Amicus or their counsel made a monetary contribution to its preparation or submission.

INTEREST OF THE AMICUS CURIAE²

As the first hand observers of hundreds of thousands of deaths each year caused by tobacco usage, the members of the American College of Chest Physicians urge this Court to recognize that unless a national approach is undertaken to regulate the sale and promotion of tobacco products, our children will continue to become morbidity statistics with one third of those using tobacco products dying prematurely. It is for this reason that the American College of Chest Physicians supports the FDA's rule restricting the sale and promotion of tobacco products to children, 61 Fed. Reg. 44,396 (1996), and seeks reversal of the Fourth Circuit's ruling. In their briefs, Petitioner and the Amici analyze the legal aspects of FDA jurisdiction. It is not our purpose to repeat those arguments. We believe, however, that a decision as to whether tobacco products fall within the jurisdiction of the FDA under the FDCA is intimately intertwined with the medical evidence related to the health hazards associated with smoking and the addictive nature of nicotine in tobacco leaves and tobacco smoke. The overwhelming medical, scientific, and internal tobacco industry evidence demonstrates that our children are anything but immune to these health hazards and will more than likely fall prey to the addictive nature of nicotine unless something is done on a national level to shield them from nicotine addiction and the resulting diseases and death associated with the use of tobacco products.

² Counsel to the American College of Chest Physicians consulted extensively with Richard D. Hurt, M.D., FACP, Professor of Medicine, Mayo Medical School, Director, Mayo Nicotine Dependence Center; D. Robert McCaffree, M.D., FCCP, Chief of Staff, University of Oklahoma, Health Science Center; Edward C. Rosenow, III, M.D., Master FCCP, MACP, Emeritus Professor, Mayo Medical School; Diane E. Stover, M.D., FCCP, Div. Head-Gen Med., Sloan Kettering Cancer Center; and John E. Studdard, M.D., FCCP, Jackson Pulmonary Associates. Additionally, Alvin Lever, Executive Vice President and Chief Executive Officer of the American College of Chest Physicians, and Lynne G. Marcus, Vice President, Membership and Public Affairs of the American College of Chest Physicians, contributed significantly to the writing of this brief.

Identity of the Amicus

The American College of Chest Physicians ("ACCP"), founded in 1935 as a medical and scientific society, is dedicated to providing postgraduate medical education for physicians, surgeons and allied health professionals involved in the diagnosis and treatment of chest diseases, including those long-term debilitating cardiopulmonary diseases induced by or exacerbated by inhalation of tobacco smoke, e.g., lung cancer, emphysema, coronary artery disease, arteriosclerosis obliterans affecting the lower extremities, bronchitis and asthma. Specialties represented by members are pulmonary disease, cardiology, cardiothoracic surgery, critical care medicine, anesthesiology, infectious disease, allergy, and related specialties. Approximately 13,000 members practice medicine and surgery in the United States and Canada and another 1,800 members practice in ninety countries worldwide. Members of the ACCP are professionally involved with the adverse effects of smoking, treating those patients who suffer from heart and lung disease on a daily basis. Every Fellow of the ACCP during the last ten years has pledged to promote the cessation of smoking among his or her patients (see Appendix A). This pledge reflects the ACCP's sincere goal to reduce or prevent cardiopulmonary disease.

As physicians, we confront on a daily basis debilitating disease and death that result from inhalation of tobacco smoke. In this century more people have died of the adverse effects of tobacco than in all the wars combined. It kills more people than AIDS, car accidents, alcohol, homicides, illegal drugs, suicides and fires combined.³ With over 400,000 deaths annually attributable to the effects of smoking, smoking diseases, such as lung cancer, emphysema, and coronary artery disease, and other cardiopulmonary diseases have become a major socioeconomic problem of transcending importance. Treatment of these diseases will continue to drain over \$800 billion from the Medicare

³ B.S. Lynch, R.S. Bonnie, eds. *Growing Up Tobacco Free: Preventing Nicotine Addiction In Children And Youths*. National Academy Press, 1994, at 3.

Trust Fund. The Veterans Administration spends over one-half billion dollars annually on inpatient care of smoking-related diseases.⁴ There are over 40 diseases/conditions that are caused by or aggravated by the use of tobacco. Thus, it is by far the most preventable cause of illness and of premature death in this country. With the exception of dying suddenly from a heart attack or stroke, the vast majority of these people die a chronic, lingering, long-suffering and expensive death.

The concern of the Amicus is magnified by the fact that tobacco smoke contains a powerful addictive drug, nicotine. Because of this highly addictive substance, many individuals find it exceptionally difficult, if not impossible, to stop smoking even when they want to, as do at least 50% of teenagers, or when their physicians advise them of the dangers to their health.

Medical science has made giant strides in eliminating some diseases that have afflicted populations in the United States and throughout the world. The ACCP continues to seek new and improved treatments and procedures (including surgery) to ameliorate the effects of diseases resulting from the direct and indirect inhalation of tobacco smoke. But, unlike other diseases which medical science has conquered or substantially reduced, elimination or control of smoking diseases is thwarted by nicotine addiction that renders normal precautionary advice and warnings ineffective.

The ACCP respectfully urges this Court to consider the medical, historical context and, in particular, the powerful addictive nature of tobacco smoke in its deliberation over the nationally important issues presented by this case.

SUMMARY OF THE ARGUMENT

The tobacco industry has known but has surreptitiously hidden evidence for decades that nicotine, the addictive agent in tobacco, is a drug which causes adverse health effects, often

⁴ 1992 Annual Report of the Secretary of Veterans Affairs, U.S. Dept. of Veterans Affairs (March 1993).

times leading to chronic illness and death. Overwhelming medical evidence indicates that the younger one starts smoking, the more debilitating are the health effects associated with tobacco usage. Internal industry research has revealed that the tobacco industry capitalized on children's inability to exercise mature judgments and thus their inability to make appropriate choices. Recognizing this, the industry purposefully directed its sales and promotion efforts to the teenage population of this country.

The totality of medical evidence compels the social and legal conclusion that something needs to be done on a national scale to protect our children against the devastating effects of nicotine and tobacco usage. Unless the FDA is found to have the legal authority to regulate the sale and distribution of cigarettes and smokeless tobacco to children and adolescents, this population will continue to be targeted by the industry thereby accelerating the likelihood that they will be plagued with the chronic illnesses associated with nicotine addiction and tobacco usage. The preponderance of medical evidence mandates that nicotine be treated as a drug and accordingly, that the FDA be found to have the legal authority to regulate tobacco products.

ARGUMENT

THE LEGAL AUTHORITY OF THE FDA TO REGULATE THE SALE AND PROMOTION OF TOBACCO PRODUCTS TO CHILDREN IS ESSENTIAL, AS THIS VULNERABLE POPULATION IS IN NO POSITION TO PROTECT ITSELF AGAINST THE ADDICTIVE NATURE OF NICOTINE, A DEBILITATING DRUG WHICH IS CAUSALLY RELATED TO CHRONIC DISEASE AND DEATH. ACCORDINGLY, THE FOURTH CIRCUIT'S DECISION SHOULD BE REVERSED.

A. What The Industry Failed To Tell Us

While the 1988 Surgeon General's Report entitled "Nicotine Addiction" is considered by most experts as the first comprehensive scientific document on the issue, it is now known that decades before, the tobacco industry identified nicotine as

the addictive agent in cigarette smoke.⁵ In fact, if the Advisory Committee to the Surgeon General in 1964 had available to it internal tobacco company research documents, it very well could have come to the conclusion at that time that nicotine was addictive. However, information contained in tobacco company files was not turned over as indicated by a July 4, 1963, letter from British American Tobacco to Addison Yeaman, lead counsel for Brown & Williamson ("B&W"), expressing the opinion of British American Tobacco senior scientist Sir Charles Ellis: "TRC consultant scientists advise it is too early to submit Battelle reports to Surgeon General's Committee . . . Charles' view is that as the situation has now developed, it would be wiser for B&W not to take the initiative in submitting anything to the Surgeon General's Committee but rather wait and hope that the Committee will ask individual manufacturers for further details of their research work . . .".⁶

Most of this information has since become public as a result of documents released during the Minnesota tobacco trial of 1998. For example, in 1962, Sir Charles Ellis, of British American Tobacco, stated, "... we now possess a knowledge of the effects of nicotine far more extensive than exists in published scientific literature . . . We believe that we have found possible reasons for addiction in two other phenomena that accompany steady absorption of nicotine. Experiments have so far only been carried out with rats, but with these it is found that certain rats become tolerant to repeated doses and after a while show the usual nicotine reactions but only on a very diminished scale. . . . Supposing the tranquilizing action of nicotine can be tracked down in this way, then these reactions will be compared in the case of rats who have never had nicotine, or alternatively have become addicted to it. Subsequent similar measurements

⁵ R.D. Hurt, C.R. Robertson, *Prying Open the Door to the Tobacco Industry's Secrets About Nicotine: The Minnesota Tobacco Trial*, 280 JAMA 1173-1181 (1998).

⁶ Letter to A.Y. Yeaman (July 4, 1963). Trial Exhibit #13905.

will be made on human nonsmokers and on addicted smokers."⁷ In a 1978 B&W memo from H. D. Steele to M. J. McCue, Steele stated, "Very few consumers are aware of the effects of nicotine, i.e., its addictive nature and that nicotine is a poison."⁸ Other memos were much more blunt. A 1983 B&W memo stated, "Nicotine is the addicting agent in cigarettes."⁹

B. How Nicotine Works To Addict

Pharmacologically, nicotine enters the blood stream rapidly from the lungs and is distributed to the brain, where it affects the central nervous system. More particularly, nicotine acts on specific receptors in specific areas of the brain (the mesolimbic system) which produce the pleasure and reward phenomenon which is a reinforcer of nicotine addiction. These effects are mediated by the neurotransmitter dopamine which is released in large quantities by nicotine. The Surgeon General's Report of 1988 stated, "The pharmacologic and behavioral process that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine." The following criteria, used to determine substance dependence, were developed by a task force of experts and published by the American Psychiatric Association as the Diagnostic and Statistical Manual of Mental Disorders—Fourth Edition ("DSM-IV"). Substance Dependence: A maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by three (or more) of the following, occurring at any time in the same 12-month period:

- 1) tolerance
- 2) withdrawal

⁷ C. Ellis, Proposal for Further Research Contracts with Battelle: *The Effects of Smoking* (February 13, 1962). Trial Exhibit #11938 from *State of Minnesota et al. v. Philip Morris Inc., et al.*, 551 N.W2d 490 (1996). Hereinafter, all references to Trial Exhibits refer to this case. These Trial Exhibits can be viewed on the Internet at <<http://www.mnbluecrosstobacco.com>>.

⁸ Memorandum from H.D. Steele to M.J. McCue, *Future Consumer Reaction to Nicotine* (August 24, 1978) (emphasis supplied). Trial Exhibit #13677.

⁹ Memorandum from A.J. Mellman to R.A. Blott, *Project Recommendations* (March 25, 1983). Trial Exhibit #13344.

- 3) the substance is often taken in larger amounts or over a longer period than was intended
- 4) persistent desire or unsuccessful efforts to cut down or control substance use
- 5) a great deal of time is spent in activities necessary to obtain the substance
- 6) important social, occupational, or recreational activities are given up or reduced because of substance use
- 7) the substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance

DSM-IV diagnostic criteria for nicotine withdrawal are:

Abrupt cessation of nicotine use, or reduction in the amount of nicotine used, followed within 24 hours by four (or more) of the following signs:

- 1) insomnia
- 2) irritability, frustration, or anger
- 3) anxiety
- 4) difficulty concentrating
- 5) restlessness
- 6) decreased heart rate
- 7) increased appetite or weight gain

Though not included in the diagnostic criteria, craving is an important element in nicotine withdrawal and may account for the difficulty that individuals have in giving up nicotine-containing products.

C. Nicotine the Addicting Drug and the Threshold Dose of Nicotine

For cigarettes, as with all drug delivery devices, it is critical to ensure that the drug (i.e. nicotine for cigarettes) is delivered to the recipient within a dose range window, the upper bound dictated by toxicity and the lower bound defined by the minimal dose required to achieve the desired pharmacological effect: in

this case nicotine addiction. Recent proposals from the scientific community have called for consideration of reducing the absolute level of nicotine in cigarettes to a point where children who experiment with cigarettes would not be able to become dependent.¹⁰ The industry also focused on this "threshold dose" but from the opposite perspective, i.e., not to avert addiction but to maintain it. A 1980 Lorillard document summarized the goals of an internal task force, one of which was to, "Determine the minimum level of nicotine that will allow continued smoking. We hypothesize that below some very low nicotine level, diminished physiological satisfaction cannot be compensated for by psychological satisfaction. At this point, smokers will quit or return to higher T&N (*tar and nicotine*) brands."¹¹

For decades, industry scientists, executives and lawyers have known full well that nicotine is addicting and that they are in the business of developing, manufacturing and selling a drug delivery device—the cigarette. "No one has ever become a cigarette smoker by smoking cigarettes without nicotine."¹²

D. The Deception of the Century: "Low Tar, Low Nicotine Cigarettes"

A December 1976 Lorillard document outlined the impression most people had (and still have) about low tar and nicotine cigarettes: "People believe that cigarettes low in tar and nicotine have different 'tobacco' ingredients and different kinds of filters than other cigarettes—the tobacco is milder or a special mild blend, perhaps treated to remove tar and nicotine, perhaps mixed with additives or fillers, perhaps cured differently—or maybe just more loosely packed . . . Those who smoke low tar

¹⁰ N.L. Benowitz, J.E. Henningfield, *Establishing A Nicotine Threshold for Addiction*, 331 New Eng. J. Med., 123-125 (1994).

¹¹ Memorandum from R.E. Smith to J.R. Ave, J.G. Flinn and A.W. Spears (February 13, 1980). Trial Exhibit #10170.

¹² W.L. Dunn, Jr., *Motives and Incentives in Cigarette Smoking* (1972). Trial Exhibit #18089.

and nicotine cigarettes generally do so because they believe such cigarettes are 'better for you'."¹³

Industry scientists were well aware that smokers compensated by taking more puffs and/or larger puffs when smoking low tar/low nicotine products. Thus, the amount of nicotine ingested was similar to that from full flavor cigarettes. A 1978 British Tobacco Company document by D. E. Creighton defined compensation to mean "subconscious changes made to the smoking pattern by a smoker in an attempt, which may or may not be successful, to equalize the deliveries of products which have different deliveries when smoked by machine under standard conditions."¹⁴ He went on to say: "[T]here is now sufficient evidence to challenge the advice to change to a lower delivery brand, at least in the short-term. In general, a majority of habitual smokers compensate for changed delivery, if they change to a lower delivery brand than their usual brand. If they choose a lower delivery brand which has a higher tar to nicotine ratio than their usual brand (which is often the case with lower delivery products), the smokers will in fact increase the amounts of tar and gas phase that they take in, in order to take the same amount of nicotine."¹⁵

E. Free-Basing Nicotine and the Importance of Speed in Developing and Sustaining Nicotine Addiction

For over three decades the industry worked to alter the chemical form of nicotine to increase the percentage of free base nicotine delivered to smokers. As a naturally occurring base, nicotine favors the salt form at low pH levels ("pHs") and the free base form at higher pHs. Free base nicotine transits biological membranes with considerably less resistance than does the "bound" form.

¹³ The Nowland Organization, Inc., Management Report: SHF Cigarette Marketplace Opportunities Search and Situation Analysis, Volume II (December 1976). Trial Exhibit #17994.

¹⁴ D.E. Creighton, Compensation for Changed Delivery (June 27, 1978). Trial Exhibit #11089.

¹⁵ *Id.*

The industry was well aware of these properties. A 1966 British American Tobacco report noted: "It would appear that the increased smoker response is associated with nicotine reaching the brain more quickly. . . . On this basis, it appears reasonable to assume that the increased response of a smoker to the smoke with a higher amount of extractable nicotine (*not synonymous with but similar to free base nicotine*) may be either because this nicotine reaches the brain in a different chemical form or because it reaches the brain more quickly."¹⁶ The report goes on to say that for both tobacco and smoke, the higher the pH, the greater the percentage of extractable nicotine. A 1971 Liggett memo stated, "Increasing the pH of a medium in which nicotine is delivered increases the physiological effect of the nicotine by increasing the ratio of free base to acid salt form, the free base form being more readily transported across physiological membranes. We are pursuing this project with the eventual goal of lowering the total nicotine present in smoke while increasing the physiological effect of the nicotine which is present, so that no physiological effect is lost on nicotine reduction."¹⁷

Industry scientists were well aware of the effect of pH on the speed of absorption and the physiologic response. A 1973 R.J. Reynolds ("RJR") report stated, "Since the unbound nicotine is very much more active physiologically, and much faster acting than the bound nicotine, the smoke at a high pH seems to be strong in nicotine. Therefore, the amount of free nicotine in the smoke may be used for at least a partial measure of the physiological strength of the cigarette."¹⁸

By the early 1970's it was recognized throughout the industry that pH alterations could serve as a means to change the

¹⁶ J.D. Blackhurst, *Further Work on 'Extractable' Nicotine*. Report issued by I.W. Hughes (September 30, 1966). Trial Exhibit #17825.

¹⁷ R.K. Williams, *Development Of A Cigarette With Increased Smoke pH* (December 16, 1971). Trial Exhibit #11903.

¹⁸ J.D. Woods, G.C. Harllee, *Historical Review of Smoke pH Data and Sales Trends for Competitive Brand Filter Cigarettes* (May 10, 1973). Trial Exhibit #12337.

form of nicotine to a more physiologically active configuration. In a 1973 RJR memo, Frank Colby said, "Still, with an old style filter, any desired additional nicotine 'kick' could be easily obtained through pH regulation."¹⁹ In another RJR memo from 1976, McKenzie said, "The pH also relates to the immediacy of the nicotine impact. As the pH increases, the nicotine changes its chemical form so that it is more rapidly absorbed by the body and more quickly gives a 'kick' to the smoker."²⁰ A 1973 RJR document stated, "Methods which may be used to increase smoke pH and/or nicotine 'kick' include: (1) increasing the amount of (strong) burley in the blend, (2) reduction of casing sugar used on the burley and/or blend, and (3) use of alkaline additives, usually ammonia compounds, to the blend."²¹

By the mid 1980's all the major cigarette manufacturers were engaged in pH manipulation of cigarette smoke, and this was seen as a way to compete in the marketplace. In a 1989 B&W document, Johnson said, "AT (*ammonia technology*) is the key to competing in smoke quality with PM (*Philip Morris*) worldwide. All U.S. manufacturers except Liggett use some form of AT on some cigarette products."²² Philip Morris commenced use of ammonia in their Marlboro brand in the mid 1960s, and it subsequently emerged as the leading national

¹⁹ Memorandum from F.G. Colby to R.A. Blevins, Jr., *Cigarette Concept to Assure RJR a Larger Segment of the Youth Market* (December 4, 1973). Trial Exhibit #12464.

²⁰ Memorandum from J.L. McKenzie to A.P. Ritchy, *Product Characterization Definitions And Implications* (September 21, 1976). Trial Exhibit #12270.

²¹ C.E. Teague, *Implications and Activities Arising From Correlation of Smoke pH with Nicotine Impact, Other Smoke Qualities, and Cigarette Sales* (1973). Trial Exhibit #13155.

²² R.R. Johnson, *Ammonia Technology Conference Minutes*, Louisville, KY, May 18-19, 1989 (June 12, 1989). Trial Exhibit #13069.

brand. Reverse engineering by Philip Morris' competitors eventually led each one to the conclusion that ammoniation in some form was "the secret of Marlboro".²³

Perhaps the most insidious aspect of ammonia technology was the recognition in the industry that the FTC testing method for determining tar and nicotine in smoke could be made meaningless. Not only does the testing method fail to accurately reflect a smoker's tar and nicotine intake, the method only measures the nicotine in the particulate or aerosol phase and is incapable of assessing the "form," i.e. bound or free base, in which nicotine exists. Further understanding of this was evident in another B&W document from 1984: "The amount of nicotine in the vapor phase can be modified by changing the acidity (pH) of the smoke. Hence it is readily feasible to have two cigarettes which deliver the same amount of nicotine (as measured on a Cambridge pad—the *FTC method*) but which are easily differentiated on the sensory basis of impact since the acidity of the smoke (and hence amount of nicotine in the vapor phase) is different."²⁴ Woods from RJR also was aware of this concept as early as 1973. "The FTC 'tar' and nicotine has decreased for all brands studied at about the same rate. Thus, all the brands have about the same FTC 'tar' and nicotine, but the Marlboro and Kool are stronger due to a higher smoke pH."²⁵ A 1973 RJR document explained, "All evidence indicates that the relatively high smoke pH (high alkalinity) shown by Marlboro (and other Philip Morris brands) and Kool is deliberate and controlled."²⁶ Graphs in this document plotted sales vs. pH vs. free base nicotine for Winston and Marlboro;

²³ See Johnson, *Ammonia Technology Conference Minutes* (June 12, 1989).

²⁴ Memorandum to Dr. L.C.F. Blackman and Mr. A.M. Heath, *Proceedings Of The Smoking Behavior-Marketing Conference*, July 9-12, 1984, session I (July 30, 1984). Trial Exhibit #13430.

²⁵ See Woods, *Historical Review of Smoke pH Data and Sales Trends for Competitive Brand Filter Cigarettes* (May 10, 1973).

²⁶ See Teague, *Implications and Activities Arising from Correlation of Smoke pH With Nicotine Impact, Other Smoke Qualities, and Cigarette Sales* (1973).

the graphs show that Marlboro sales increased as the pH and percent free base nicotine increased for the years 1955 through the early 1970's. Additional evidence of the industry's investigation into pH manipulation comes from a 1994 Philip Morris document, "To illustrate, a study was conducted on nicotine aerosols, where subjects inhaled the same amount of nicotine at pHs of 5.6, 7.5 and 11.0. It was found that higher peak concentrations of nicotine in blood were achieved at higher pHs. Since the amounts of inhaled nicotine were the same, the results indicate that the higher the pH, the more rapidly nicotine enters the bloodstream."²⁷

Ammonia compounds are among the most abundant additives used in the manufacture of cigarettes in this country. The industry contends that ammonia compounds are added for taste, not to "free base" the nicotine. However, neither the science nor internal industry documents support that contention.

F. Cigarettes: A Product of a Tobacco or Drug Industry?

That nicotine is a drug, the cigarette a delivery device and tobacco companies are in the drug business, has not escaped the focus of the industry. Claude E. Teague, Jr., Assistant Director of Research at RJR could have been speaking for the entire industry in a 1972 memorandum: "In a sense, the tobacco industry may be thought of as being a specialized, highly ritualized and stylized segment of the pharmaceutical industry. Tobacco products, uniquely, contain and deliver nicotine, a potent drug with a variety of physiological effects. . . . Thus a tobacco product is, in essence, a vehicle for delivery of nicotine, designed to deliver the nicotine in a generally acceptable and attractive form. Our Industry is then based upon design, manufacture and sale of attractive dosage forms of nicotine, and our Company's position in our Industry is determined by our ability to produce dosage forms of nicotine which have more overall value, tangible or intangible, to the consumer than those of our

²⁷ *The Effects of Cigarette Smoke "pH" on Nicotine Delivery and Subjective Evaluations* (June 24, 1994). Trial Exhibit #11752.

competitors. . . . If nicotine is the sine qua non of tobacco products and tobacco products are recognized as being attractive dosage forms of nicotine, then it is logical to design our products—and where possible, our advertising—around nicotine delivery rather than "tar" delivery or flavor. . . . If, as proposed above, nicotine is the sine qua non of smoking, and if we meekly accept the allegations of our critics and move toward reduction or elimination of nicotine from our products, then we shall eventually liquidate our business. If we intend to remain in business and our business is the manufacture and sale of dosage forms of nicotine, then at some point we must make a stand."²⁸

Publicly admitting that nicotine is a drug had potential regulatory implications. In a 1969 Philip Morris document, Dunn wrote to H. Wakeham, Director of R&D, "I would be more cautious in using the pharmacomedical model—do we really want to tout cigarette smoke as a drug? It is, of course, but there are dangerous FDA implications to having such conceptualization go beyond these walls."²⁹ Dunn expressed similar concerns in a 1980 letter to R. B. Seligman: "Any action on our part, such as research on the psychopharmacology of nicotine, which implicitly or explicitly treats nicotine as a drug, could well be viewed as a tacit acknowledgment that nicotine is a drug. Such acknowledgment, contend our attorneys, would be untimely."³⁰ A. D. McCormick at British American Tobacco in 1974 was also concerned about the FDA: "If tobacco were to be placed under a Food and Drug law, classification of tobacco under the food section would be acceptable, but classification of

²⁸ Memorandum from C.E. Teague, Jr., *The Nature of the Tobacco Business and the Crucial Role of Nicotine Therein* (April 14, 1972). Trial Exhibit #12408.

²⁹ Memorandum from W.L. Dunn, Jr. to Dr. H. Wakeham, *Jet's Money Offer* (February 19, 1969). Trial Exhibit 10539.

³⁰ Memorandum from W.L. Dunn to R.B. Seligman, *The Nicotine Receptor Program* (March 21, 1980). Trial Exhibit #26227.

tobacco as a drug should be avoided at all costs."³¹ In a 1980 memo to R. B. Seligman and Directors of Philip Morris, Thomas Osden outlined the priorities for "Evaluation of Major R&D Programs".³² About the nicotine program, he stated, "This program includes both behavioral effects as well as chemical investigation. My reason for this high priority is that I believe the thing we sell most is nicotine."³³

The concept of the cigarette as a drug delivery device is deeply rooted in the industry. W. L. Dunn, in a 1972 Philip Morris document, summarized the discussion at a conference attended by 25 scientists from England, Canada and the United States: "The majority of conferees would accept the proposition that nicotine is the active constituent of cigarette smoke. . . . The cigarette should be conceived not as a product but as a package. The product is nicotine."³⁴

Researchers at British American Tobacco wrote, "BAT should learn to look at itself as a drug company rather than as a tobacco company."³⁵ Finally, Addison Yeaman, General Counsel of B&W, said more than three decades ago, "We are, then in the business of selling nicotine, an addictive drug."³⁶

G. Marketing to Children—Is "addiction" really free choice?

The tobacco industry argues that the decision to smoke and to continue smoking is a free choice made by adults. The main problem with this defense is that nicotine addiction is a

³¹ Memorandum from A.D. McCormick, *Smoking and Health* (May 3, 1974). Trial Exhibit #10602.

³² Letter from T.S. Osden to R.B. Seligman, *Evaluation of Major R&D Programs* (August 12, 1980). Trial Exhibit #10255.

³³ *Id.*

³⁴ See Dunn, *Motives and Incentives in Cigarette Smoking*.

³⁵ R.A. Crellin, *Brainstorming II: What Three Radical Changes Might, Through the Agency of R&D, Take Place in this Industry by the End of the Century?* (April 11, 1980). Trial Exhibit #11361.

³⁶ P. Hilts, *Tobacco Company Was Silent on Hazards*, New York Times, 1994, at 1.

condition that begins for most in childhood.³⁷ Furthermore, the "choice" argument is impossible to defend in the face of nicotine addiction because children may "choose" to experiment with cigarettes, but they do not choose to become addicted. The reason for the tobacco industry's public denial of nicotine addiction was clearly stated in a 1980 Tobacco Institute document which said: "Shook, Hardy (Shook, Hardy and Bacon, L.L.P., is a Kansas City law firm that has directed legal strategy for the tobacco industry³⁸) reminds us, I'm told, that the entire matter of addiction is the most potent weapon a prosecuting attorney can have in a lung cancer/cigarette case. We can't defend continued smoking as 'free choice' if the person was 'addicted'.³⁹

Most adult smokers start smoking before the age of 18, a fact that has been well known by the tobacco industry and its marketing departments for decades. For example, in a report to the Board of Directors of RJR on September 30, 1974, entitled, "1975 Marketing Plans Presentation, Hilton Head, September 30, 1974," one of the key opportunities to accomplish the goal of re-establishing RJR's market share was proclaimed to be: "[I]ncrease our young adult franchise. . . . First, let's look at the growing importance of this young adult in the cigarette market. In 1960, this young adult market, the 14-24 age group,

³⁷ D. Kessler, *Nicotine Addiction in Young People*, 333 New Eng. J. Med., 186-189 (1995).

³⁸ S.A. Glantz, D.E. Barnes, L. Bero, P. Hanauer, J. Slade, *Looking Through a Keyhole at the Tobacco Industry: The Brown and Williamson documents*, 274 JAMA 219-224 (1995); P. Hanauer, J. Slade, D.E. Barnes, L. Bero, S.A. Glantz, *Lawyer Control of Internal Scientific Research to Protect Against Products Liability Lawsuits: The Brown and Williamson documents*, 274 JAMA 234-240 (1995); L. Bero, D.E. Barnes, P. Hanauer, J. Slade, S.A. Glantz, *Lawyer Control of the Tobacco Industry's External Research Program: The Brown and Williamson documents*, 274 JAMA 241-247 (1995).

³⁹ Memorandum from P.C. Knopick to W. Kloepper (September 9, 1980). Trial Exhibit #14303.

represented 21 percent of the population. . . . They will represent 27% of the population in 1975. They represent tomorrow's cigarette business."⁴⁰

The first strategy listed was: "1—Direct advertising appeal to the younger smokers . . .".⁴¹ These marketing plans became the marketing goals under RJR's 1975 domestic operating goals.⁴²

In a 1980 RJR document entitled, "MDD Report on Teenage Smokers (14-17)", a future CEO, G. H. Long, wrote to the CEO at that time, E. A. Horrigan, Jr. In this document, Long is lamenting the loss of market share of the 14- to 17-year-old smokers to Marlboro. "Hopefully, our various planned activities that will be implemented this fall will aid in some way in reducing or correcting these trends."⁴³

That the industry focused a lot of attention on children was evident in other documents such as a survey performed for Philip Morris in 1974⁴⁴ in which children age 14 or younger were being interviewed about their smoking behavior⁴⁵ and in a 1979 Philip Morris document which said amongst other things, "Marlboro dominates in the 17 and younger category, capturing over 50 percent of this market."⁴⁶ When 30% of 3 year olds and nearly 90% of 5 year olds associate a picture of "Joe Camel" with cigarettes⁴⁷, it is obvious that these directed marketing efforts are extremely influential.

⁴⁰ C.A. Dukes, 1975 Marketing Plans Presentation to RJRI Board of Directors (September 30, 1974). Trial Exhibit #12493.

⁴¹ *Id.*

⁴² *Domestic Operating Goals* (November 26, 1974). Trial Exhibit #12377.

⁴³ Memorandum from G.H. Long to E.A. Horrigan, Jr., *MDD Report on Teenage Smokers (14-17)* (July 22, 1980). Trial Exhibit #13101.

⁴⁴ The Roper Organization Inc., *A Study of Smoking Habits Among Young Smokers* (July 1974). Trial Exhibit #10497.

⁴⁵ G. Bible, Minnesota Tobacco Trial Transcript at 6097 (March 8, 1998).

⁴⁶ Marlboro (March 29, 1979). Trial Exhibit #11808.

⁴⁷ MacKensie et al., *New Eng. J. Med.*, April 7, 1994, at 975-80.

H. How Nicotine Addiction Affects Our Nation's Youth

Three thousand children start smoking every day.⁴⁸ Of these 3000, in their lifetime, 23 will be murdered, 30 will die in an automobile accident and more than 1000 will die prematurely from smoking related diseases. Approximately two-thirds of people who smoke begin by age 14 and over 90% do so by age 19. The number of college students who have smoked in the last 30 days rose by nearly 28% from 1993 to 1997. In some states the rate of smoking among high school students has risen by 70%.

These statistics are overwhelming especially in light of the health hazards associated with tobacco smoking by children. Children that begin smoking at age 15 have twice the incidence of lung cancer as do those who start at age 25.⁴⁹ Of additional concern are more recent findings of the adverse effects noted very early on in young smokers. Their heart rates are 2 to 3 beats per minute faster than nonsmokers.⁵⁰ Changes of the arterial inner wall that will lead to hardening of the arteries are evident.⁵¹ A study of 10- to 18-year-old smokers found statistical evidence of airway function impairment (possibly early emphysema) and slowed growth of lung function.⁵² Genetic mutations can be found in newborns of smoking mothers that predispose their children to blood malignancies in childhood.⁵³ Smoking mothers have higher spontaneous abortion rates and lower birth weight babies. These babies suffer from respiratory distress, pneumonia and higher neonatal death rates. Maternal smoking has been shown to cause a "catastrophic disruption" of the chromosomes in human eggs that can lead to miscarriages

⁴⁸ 1994 Surgeon General's Report, *Preventing Tobacco Use Among Young People*.

⁴⁹ *Cigarette Smoking and Health*, *Am. J. Respir. Crit. Care Med.*, Vol. 153 at 861-5 (1996).

⁵⁰ See 1994 Surgeon General's Report, at 28.

⁵¹ Celemajer et al., *New Eng. J. Med.*, January 18, 1996, at 150-4.

⁵² Gold et al., *New Eng. J. Med.*, September 26, 1996, at 931-7.

⁵³ Finette et al., *Nature Medicine*, October 1998, at 1144-51.

as well as cause chromosome changes associated with lymphoma. Another study found that benzopyrene produces genetic changes typical of those seen in human lung cancer.⁵⁴ The earlier one begins to smoke, the greater these changes. And if this is not enough, it should not be overlooked that nicotine is an introductory drug ("gateway drug"), as smokers are 15 times more likely to become an alcoholic, to become addicted to "hard drugs" or to develop a problem with gambling.

CONCLUSION

Nicotine is a powerful, addictive drug. We, the treating physicians, know it. The industry, despite its many attempts to deny or dilute the truth, knows it. But do our children know it? And if they know it, does it mean that they truly understand the consequences of nicotine addiction? The answer to this question is no. No sane person would consciously choose the inevitable diseases and resulting death associated with tobacco use. Like all other drugs, it is essential that the FDA have the legal authority to regulate the sale and promotion of tobacco products. Children are the least likely population to exercise "free choice". The younger these kids start smoking, the more powerful the addiction is to nicotine. The stronger the addiction, the harder it is to stop. The longer they smoke, the shorter they live. For these reasons, we respectfully request this Court to reverse the Fourth Circuit's ruling and find that the FDA has the legal authority to regulate tobacco usage among minors.

⁵⁴ Denissenko et. al., Science, October 18, 1996, at 430-2.

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Appendix A**PLEDGE**

As a Fellow of American College of Chest Physicians and a leader in the most important struggle faced by chest physicians, the prevention and control of our major health problems of lung cancer, cardiovascular and chronic pulmonary disease, I shall make a special personal effort to control smoking and to eliminate this hazard from my office, clinic, and hospital. I shall ask all of my patients about their smoking habits, and I shall assist the cigarette smoker in stopping smoking. I make this pledge to my patients and to society.